Innovative Contracting for Better Material Transfers

Karen E. Sandrik*

Empirical studies find that contrary to expected outcomes, it is not patents that most often impede research. Instead, it is access to tangible research inputs that is more likely to cause the delay or abandonment of promising research. Difficulty in the negotiation and execution of material transfer agreements (MTAs), the contractual agreements governing the transfer of materials, research tools, and data, is the cause. This Article addresses a new trend in MTA practice that is both exciting and problematic.

In the past, MTAs largely functioned as a recording mechanism to track who had what materials and to set expectations in the case of a laboratory accident or infringement lawsuit involving the transferred material. Now, however, some industry parties are using MTAs to gain more than just a record of the transfer and basic representations and warranties. Industry parties are using MTAs to develop and build relationships. This, in turn, is leading to more shared innovative activity,

* Assistant Professor, Willamette University College of Law. For helpful comments, suggestions, and encouragement, I thank Curtis Bridgeman, David Friedman, John Golden, Robert Gomulkiewicz, Sean O. Connor, Liza Vertinsky, Norman Williams, and participants at a Florida State University Summer Workshop, June 2014, the Intellectual Property Scholars Conference at the UC-Berkeley, August 2014, and the Pacific Intellectual Property Scholars Conference at the University of Washington and Seattle University, February 2015. Special thanks goes to Andrew Lee for his excellent research assistance. All errors are my own.

a key factor in moving scientific fields forward. Yet this progress towards more shared innovative activity is not without cost. Most notably, this modern MTA practice is increasing transaction costs and the likelihood of bargaining breakdowns because not everyone is using MTAs in this way. In order to facilitate access to materials, tools, and data while also furthering shared innovative activity, non-industry parties, most notably, academic institutions, should join the modern MTA regime. Lawyers have an opportunity to improve the material transfer process through innovative contracting practices. This Article provides suggestions on how to accomplish this by overcoming contested terms and using a modern MTA to give access to materials and help develop collaborative relationships.

Introduction

Shared innovative activity is the key to the progression of science.[1] In today's sophisticated world, it is rare for an isolated researcher to discover or invent something new. Instead, new discoveries, products, and inventions require a team of researchers spanning academic institutions, research laboratories, and industry to come together to share researchers' expertise, laboratory space and equipment, materials, and general know-how and expenses. The future of science is this togetherness. How best to support the foundation of shared innovative activity through access to tangible research inputs is the subject of this article.

The foundation of shared innovative activity is access—access to one another's materials, research tools, and data. Access is more problematic for researchers than are patents.[2] If a biotechnology company develops a promising oral enzyme inhibitor for the treatment of patients with a broad range of blood cancers, it will need the financial backing and expertise of a larger pharmaceutical company to move forward in development of the inhibitor and in clinical trials to bring the promising new discovery to the public.[3] Before partnering with the biotech company, an inter-

---

1 This understanding of science and innovation is apparent in statements made by individuals such as Dr. Michael Caligiuri, director of the Ohio State University Comprehensive Cancer Center and CEO of the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute. He recently explained that "[t]here is no routine cancer, and today it takes the collective minds across disciplines, institutions and industry to move the field forward." *The Ohio State University and University of Michigan Partner with Industry to Bring Oral Cancer-Fighting Patch to Patients*, THE OHIO STATE UNIVERSITY COMPREHENSIVE CANCER CENTER (June 5, 2014), http://cancer.osu.edu/news-and-media/news/ohio-state-and-university-of-michigan-partner-to-bring-oral-cancer-fighting-patch-to-patients.

2 *See* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 1060 HOUS. L. REV. 1059, 1061-62 (2008) (explaining that "[m]ore significant to researchers than patents . . . have been practical restrictions on access to materials and data, such as requirements for institutional assent to the terms of materials transfer agreements (MTAs)."). *See also* John P. Walsh, Charlene Cho & Wesley M. Cohen, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1190 (2007) (same).

3 *See, e.g.*, *Infinity and AbbVie Announce Global Strategic Collaboration to Develop and Commercialize Duvelisib (IPI-145) In Oncology*, INFINITY PHARMACEUTICALS, INC. (Sep. 3, 2014), http://phx.corporate-ir.net/phoenix.zhtml?c=121941&p=irol-newsArticle&ID=1963180.

ested pharmaceutical company will require access to the oral enzyme inhibitor, a type of "material," and its accompanying data so that the pharmaceutical company may determine the inhibitor's efficacy potential as well its compatibility with the pharmaceutical company's particular knowledge and expertise in the field of pharmacology.

The biotech and pharmaceutical companies will sign some form of a material transfer agreement ("MTA") to grant the pharmaceutical company access to the material and sometimes its accompanying data.[4] Internal policies at the majority of academic institutions, industry partners, and federal agencies require an executed MTA before a transfer. This is so even when there is no plan for further shared innovative activity.

For example, when the University of North Carolina (UNC) or the U.S. Centers for Disease Control and Prevention (CDC) needs tissue samples containing the MERS-CoV (MERS) virus in order to begin testing and learning about the virus,[5] they only want immediate access. UNC and the CDC each have their own research laboratories, scientists, and general know-how to conduct their own analysis, at least at this initial stage. Even though there is no repeated interaction desired with the transferor, both UNC and the CDC must still negotiate and execute a MTA to get access to these crucial samples.[6] With the MERS samples, MTAs were negotiated and executed by the UNC, the CDC, and at least 40 others from around the world. The majority of these MERS samples came from an academic institution in the Netherlands, a laboratory in the United Kingdom, and from Saudi Arabia.[7]

These two examples demonstrate that MTAs are used worldwide in both the collaborative partnership between biotechnology and pharmaceutical companies and the one-time interaction between the transferor and transferees of the MERS samples. And all across the world, the negotiation and execution of MTAs, as they did with the MERS-CoV outbreak, cause delays of research. Parties consistently state that "MTAs are a pain in the neck,"[8] so why do lawyers and technology transfer offices insist on the execution of MTAs prior to transfer?

---

4 Industry parties quite frequently use other terms such as licenses and collaborative agreements.

5 Jim Wappes, *WHO Raises its MERS-CoV Counts to 55 Cases, 31 Deaths*, CTR. FOR INFECTIOUS DISEASE RESEARCH AND POLICY (June 7, 2013), http://www.cidrap.umn.edu/news-perspective/2013/06/who-raises-its-mers-cov-count-55-cases-31-deaths.

6 *See, e.g.*, Robert Coos, *Saudis to Send Animal Samples to US in MERS-COV Probe*, CTR. FOR INFECTIOUS DISEASE RESEARCH AND POLICY (May 24, 2013), http://www.cidrap.umn.edu/news-perspective/2013/05/saudis-send-animal-samples-us-mers-cov-probe; Christian Nordqvist, *MERS-CoV Death Toll Rises to 31*, MEDICAL NEWS TODAY (Jun. 8, 2013, 12:00 PM), http://www.medicalnewstoday.com/articles/261671.php.

7 *See* Coos *supra* note 6; *See also* Laurie Garrett, *Why a Saudi Virus is Spreading Alarm*, COUNCIL ON FOREIGN RELATIONS (May 29, 2013), http://www.cfr.org/public-health-threats-and-pandemics/why-saudi-virus-spreading-alarm/p30799.

8 Ian M. MacKay, *Questions about MERS, MTAs, and Mistakes*, VIROLOGY DOWN UNDER BLOG (May 26, 2013), http://virologydownunder.blogspot.com/2013/08/questions-about-mers-mtas-and-mistakes.html.

To begin with, it is important to note that unlike with patents where the "burden of inertia" is on the patent holder to detect infringement and enforce its rights, the party in need of materials, tools, or data must bear the cost of finding the needed input and obtaining access.[9] In other words, one in need of a research input does not have the option to "take now, pay later."[10] Two more reasons that MTAs are so heavily used is because there is substantial risk and uncertainty in these types of transfer.[11]

Risk exists, for example, in the form of everything from patent, tort, and contract litigation to laboratory accidents and the simple but perilous handling of contaminated tissue samples.[12] Uncertainty exists when there is a sharing and developing of proprietary information. Development of this information often takes millions of dollars and many years to discover and develop. The sharing of that information necessarily involves inherently volatile collaborative relationships. Risk and uncertainty are mitigated, at least in part, and planned for, as much as is possible, if the expectations of the parties are discussed, planned, and recorded so that all may review the written contract if the transfer does not go as planned.

Even though the built-in confidential nature of MTAs makes empirical research hard to conduct, especially in industry practice, it is believed that hundreds of thousands of MTAs are signed every year globally, with academic institutions in the United States alone spending millions annually to manage their MTA practice.[13] This is significant because MTAs rarely generate money and often cause delays to research due to the lengthy negotiations and outright denial of—or lack of response to—material transfer requests. This Article identifies reasons for delays in negotia-

---

9 *See* Eisenberg, *supra* note 2, at 1062.

10 Under a "take now, pay later" rule, interested users or takers of a particular entitlement can unilaterally act, so as long as they pay the officially determined price for that entitlement. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1302 (1996).

11 Similar to others writing about contracts in the field of science and technology, when using the terms "risk" and/or "uncertainty" I am adopting H. Knight's usage. *See generally* Frank H. Knight, UNCERTAINTY AND PROFIT (1921) (differentiating "risk" from "uncertainty" as a quantity that can be measured).

12 Even simple skin coverage, particularly of sensitive areas of the body such as the eye, ear, and nose, can be difficult. As of December 2014, 335 relief workers died while fighting against transmission of the Ebola virus infections in West Africa. *US Army Adopts and Deploys Provodine® from Microdermis to Fight Ebola*, LIFE SCI. W'KLY. (Dec. 1, 2014, 12:19 PM), http://venturebeat.com/2014/12/01/us-army-adopts-and-deploys-provodine-from-microdermis-to-fight-ebola/. This number is likely to dramatically decrease in the future after a MTA recently allowed the U.S. Army Medical Research Institute of Infectious Diseases to test Provodine® to determine its antiseptic protection even of sensitive body parts after exposure to Ebola virus particles. *Id.*

13 *See Benefits of MTAShare*, VAND. UNIV., CTR. FOR TECH. TRANSFER & COMMERCIALIZATION, http://cttc.co/cttc/content/inventors/mtashare/benefits-mtashare (last visited Apr. 3, 2016) (click on MTAShare video on "Key Benefits of MTAShare").

tions as well as the high numbers of denials or failed negotiations.[14] MTAs are, at least compared to other licensing instruments in the technology transfer world, uncomplicated documents. Yet, it often takes lawyers and MTA specialists months to negotiate and execute one MTA. In the case of the so-called "Harvard oncomouse," it took four years of negotiations to permit noncommercial researchers to use the oncomice without cost.[15]

The previously proposed solutions to the increased transaction costs and bargaining breakdowns of MTAs often involve some sort of a standardized MTA. I argue here that the missing piece is not the goldilocks standardized form. This is because a new form will not solve the previously unidentified problem that is discussed here. In short, while some parties believe they are negotiating with the same objective in mind—a transferred material, tool, or data—this, in fact, is not true. The delays in execution and failed negotiations occur because MTAs serve more than one function, yet lawyers and licensing specialists have largely missed this important detail. This lack of understanding leads to misunderstandings and complaints that the other side "just doesn't get it."[16]

When parties are employing a MTA for a one-time interaction, like with the MERS example above, they are using what I will call herein a "traditional" MTA. Traditional MTAs have been in practice for decades and are the favored type of MTA of academic institutions.

Oftentimes, when academic institutions negotiate with an industry partner, however, there is tension among the transfer specialists and lawyers because the industry partner does not want a one-time interaction. Instead, the industry partner only wants to take on the transaction costs to transfer the material, tool, or data when it will lead to potential shared innovative activity. In essence, the industry partner is using the MTA to help build a collaborative relationship. I will call this use of a MTA a "modern" MTA. Whether in industry contracting practice it is called a MTA in title or not, and this varies widely, and whether or not the industry party even consciously recognizes the difference, a modern MTA serves a different function than a traditional MTA.

The modern MTA helps parties build relationships and plan for uncertainty by combining firm terms with clear obligations and soft contract terms, such as "good faith," "commercially reasonable efforts," or "diligent efforts," with terms that are

---

[14] There is also evidence that MTA requests are so numerous and taxing on resources that academic institutions and faculty members are simply ignoring them. Wendy D. Streitz & Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133 PLANT PHYSIOLOGY 1, 1 (2003), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC523866/.

[15] *See* Fiona Murray, *The Oncomouse That Roared, Hybrid Exchange Strategies as a Source of Distinction at the Boundary of Overlapping Institutions*, 116 AM. J. SOC. 2, 367 (2010), *available at* http://fmurray.scripts.mit.edu/docs/Murray_AJS_2010_653599.pdf.

[16] This is a remark that one industry MTA specialist made in frustration when discussing MTA negotiations with academic institutions.

non-remedial or unenforceable terms because they are too vague, indefinite, or speculative.[17] The combination of these varied terms allows parties to respond cooperatively to risk and uncertainty by creating, in most instances, formal boundary lines and some sort of accompanying mechanism that helps the parties flesh out more details of the agreement at a later point.

The modern MTA is a type of contract that is leading to shared innovative activity where not just materials are shared, but also scientists, laboratories, proprietary information, and marketing plans. After extensive research, including interviews with academic and industry parties, I find that the modern MTA is in use almost exclusively by industry parties.[18] Lawyers and licensing specialists at academic institutions where there is a desire to build relationships and bring upstream research into the downstream process need to recognize and employ modern MTAs. The modern MTA is not a new form to take the place of the traditional MTA; rather, it is a different way of contracting that achieves a different goal. This Article provides guidance to academic institutions and others currently using a traditional MTA who want to embrace a more innovative and modern MTA practice that fosters collaboration.

Part I of this Article traces the development of academic science and identifies the key features of the traditional MTA most often used by academic and government scientific institutions. Part II discusses industry science and identifies the key features of the modern MTA. Part III.A argues that there are still situations that the traditional MTA should be used in, but that particular contested terms leading to lengthy negotiations need addressing. This Part offers pragmatic work-around solutions for these contested terms. Part III.B argues for the adoption of the modern MTA when a one-time transaction is not desired. This Part identifies potential enforcement problems with the modern MTA and offers solutions to lawyers and contracting specialists in technology transfer offices.

---

[17] This occurs where no promise or obligation is made or incurred. Ronald J. Gilson, Charles F. Sabel, and Robert E. Scott, in a series of articles on "contracting for innovation," call this process "braiding." *See generally* Ronald J. Gilson et al, *Braiding: The Interaction of Formal and Informal Contracting in Theory, Practice, and Doctrine*, 110 COLUM. L. REV. 1377 (2010). I have added non-remedial clauses, because in my research, I found those terms are more common than legally unenforceable terms.

[18] Although I have done my best to include a representative sample of MTAs from a broad range of technological fields and varied institutions, there are noteworthy limitations to my research and sample size. MTAs often include a confidentiality requirement, making it difficult as a researcher to gain access to the full text and surrounding context of the agreement. I have done my best to overcome this access hurdle by conducting in-person and telephone interviews with multiple technology transfer specialists at academic institutions and in-house counsel and outside counsel responsible for drafting MTAs for industry parties. Even with these interviews, however, I was most successful in speaking with and gaining access to MTAs where academic institutions and biotechnology companies had partnered with publicly traded pharmaceutical companies. This success was largely based upon the fact that federal securities laws require publicly traded companies to make disclosures that frequently capture these agreements. As such, there is the potential for an industry-based bias present in this Article, one that I hope to overcome in future projects.

I. The Development of the "Traditional" MTA

The commercialization of science continues to evolve. In the twentieth century, commercial scientists generally focused on applied science while noncommercial scientists focused on basic science. The noncommercial scientists, employed at universities, teaching hospitals, and research laboratories, were thought of as "pure scientists," leaving the commercialization of their basic science discoveries to industry. This broad classification of noncommercial and commercial scientists still exists today, although the classification has been rebranded in part and the separation is now quite blurred. Today, basic science, the understanding of science, is generally termed "upstream" research or the upstream process. Conversely, applied science, the use of science, is often referred to as "downstream" research and development or the downstream process.

Just like with basic science, upstream research is focused on scientific discovery with the end goal of better understanding the subject matter at study.[19] Take Dr. Mary-Claire King, for example. Dr. King, at the time a faculty member at UC-Berkeley, received financial support from the National Cancer Institute (NIC) to study hereditary breast cancer.[20] She was not focused on creating a new therapy or diagnostic screening process at that point, but instead on making a discovery that might help her and others better understand hereditary breast cancer. Dr. King was focused on upstream research. Ultimately, it was Dr. King and her laboratory that proved there is a single genetic mutation, breast cancer susceptibility gene 1 (BRCA1), located on chromosome 17, which is responsible for inherited breast and ovarian cancers.[21]

The opposite of upstream research is downstream research. This is where scientists, most often industry scientists, are focused on developing the upstream science discoveries into a product or process to bring to the market.[22] After Dr. King's increased understanding and isolation of BRCA1, the next step was for scientists in

---

[19] *See* Meir Perez Pugatch et al., *Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights*, PUGATCH CONSILIUM (June 2012), https://www.bio.org/sites/default/files/Pugatch%20Consilium%20-%20Taking%20Stock%20Final%20Report%20(2).pdf (defining upstream process as "[t]he range of research and development activities which relate to the pre-market and development stages of a product or technology"); Ed Levy et al., *Patent Pools and Genomics: Navigating a Course to Open Science*, 16 B.U. J. SCI. & TECH. L. 75, 76 (2010) (explaining that although an imprecise term, upstream research is the type "intended to yield information or knowledge.").

[20] *See Enhancing Breast and Ovarian Cancer Care: The Discovery of BRCA1 and BRCA2*, NATIONAL CANCER INSTITUTE, (Mar. 2014), http://www.cancer.gov/aboutnci/servingpeople/cancer-research-progress/discovery/brca.

[21] After Dr. King's discovery, Dr. Mark Skolnick, again with funding from NIC, was the first to clone the gene and pinpoint its exact location. *See* Laurie McHale, *Putting the Puzzle Together*, U. WASH. (Nov. 6, 1996), https://www.washington.edu/alumni/columns/sept96/king1.html.

[22] *See* Pugatch et al., *supra* note 19 (defining downstream process as "the range of activities that relate to the market and post-market phases (including commercialization) of a new product or technology . . ."); Levy et al., *supra* note 19, at 76 (describing downstream research as "research that can directly form the basis of a product.").

the downstream process to create a diagnostic screening process for BRCA1. After the discovery of BRCA1, and shortly thereafter BRCA2, Myriad Genetics won this race after collaborating with over 444 outside scientists in its endeavor to find the most effective diagnostic test for BRAC1 and BRAC2.[23]

This once clear demarcation between noncommercial scientists focusing on upstream research and commercial scientists on downstream research is not so clear anymore. Moreover, the "distinction" between upstream and downstream research, like with basic and applied science, is largely dynamic.[24] Academic institutions are seeking to turn their upstream research into downstream development that may lead to "blockbuster" patents, and industry scientists are doing more research work in the upstream process.[25]

For example, in 2007, New York University received approximately $650 million in royalties for an autoimmune-disease-treating pharmaceutical developed by two researchers.[26] The total royalties generated are estimated at $1 billion.[27] Similarly, Northwestern University received around $700 million in royalties for a pharmaceutical treatment for seizures developed by a chemistry professor.[28] The success stories of NYU and Northwestern, among others, have motivated academic institutions to protect faculty output though patent law and contract law and then to aggressively license and enforce the patented technology. This means that academic institutions in many instances are indistinguishable from their industry counterparts.[29]

---

[23] *See* Mark C. Capone, *Setting the Record Straight: Comments on Recent Media Reports Regarding BRCA1/2 Patents*, Myriad Genetics (Apr. 23, 2010), https://www.myriad.com/lib/speaker-portal/Setting%20the%20Record%20Straight.pdf.

[24] *See generally* DONALD E. STOKES, PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION (1997) (challenging the linear model of the relationship between basic and applied science).

[25] *See, e.g.*, Ronald I. Eisenstein & David S. Resnick, *Blockbuster Patents Enrich University Coffers, but can also Affect Future Patenting and Research Decisions*, NATURE (2001), http://www.nature.com/bioent/2003/030101/full/nbt0901-881.html.

[26] *See* Karen W. Arenson, *Manhattan Drug Research Benefits University*, N.Y. TIMES, May 8, 2007, *available at* http://www.nytimes.com/2007/05/08/nyregion/08mbrfs-drug.html?_r=0.

[27] Richard Perez-Pena, *Patenting Their Discoveries Does Not Pay Off for Most Universities, a Study Says*, N.Y. TIMES, Nov. 20, 2013, at A18, *available at* www.nytimes.com/2013/11/21/education/patenting-their-discoveries-does-not-pay-off-for-most-universities-a-study-says.html.

[28] *See* Jon Van, *Drug Find Worth $700 Million*, CHI. TRIBUNE (Mar. 10, 2008), http://articles.chicagotribune.com/2008-03-10/business/0803090219_1_gaba-richard-silverman-*drug*-companies (explaining that Dr. Silverman's discovery is the "chemist's version of a Power-Ball ticket").

[29] *See, e.g.*, Peter Lee, *Patents and the University*, 63 DUKE L.J 1, 5 (2013) (stating that "academic science has become more aggressive, and universities have begun behaving more like typical commercial entities"); *see also* Mark Lemley, *Are Universities Patent Trolls?* 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008) (describing push to maximize licensing revenues as strong trend among universities today).

On the other end, industry is not only funding more research, in particular university research,[30] industry partners are themselves entering upstream efforts. This means that industry parties are focusing more on the upstream process much like academic institutions are finding themselves in the downstream process. For example, it is widely known that pharmaceutical companies play a vital role in proving or disproving medical hypotheses that noncommercial scientists put forth, but pharmaceutical and biotech companies similarly play a complementary role in the discovery of new compounds.[31] It is the discovery of these compounds in the upstream process that after much testing leads to new (downstream) pharmaceutical products.

This blurred line between upstream and downstream research and noncommercial and commercial science has many advantages. The growth of academic science into downstream research and development, for example, has lead to groundbreaking innovation. From penicillin production, to Plexiglas and the Polio and Hepatitis B vaccines, warfarin and insulin to antigens and saccharin—academic science has undeniably changed the world.[32] This innovation has also led to another positive change—a substantial amount of money poured back into science departments and research laboratories.[33]

Furthermore, there is an increased understanding that "today, it takes the collective minds across disciplines, institutions and industry to move [a] field forward."[34] Shared innovative activity can help expedite the understanding of a field, leading to new discoveries and development of targeted therapies and diagnostic tests.[35] Commentators like Henry Etzkowitz, a leading international scholar responsible for the "Entrepreneurial University" and "Triple Helix" concepts linking university re-

---

30 Justin Biddle, *Bringing the Marketplace into Science: On the Neoliberal Defense of the Commercialization of Scientific Research*, 274 SCI. IN THE CONTEXT OF APPLICATION 245, 246 (2010) (explaining that "the boundaries between business, on the one hand, and government and university research, on the other, are becoming ever more blurry").

31 *See* JOHN L. LAMATTINA, DRUG TRUTHS: DISPELLING THE MYTHS ABOUT PHARMA R&D 4 (2009) (tracing "[t]he principle of lowering LDL cholesterol" and explaining that this movement forward in understanding the relationship between heart disease and cholesterol was supported by discoveries of various compounds by a microbiologist working at the Sankyo company in Tokyo and a team of Merck chemists).

32 *See University Inventions that Changed the World*, IPADVOCATE.ORG (Nov. 10, 2009), http://www.ipadvocate.org/pdfs/Uni%20Inventions%20Changed%20the%20World.pdf.

33 Many of the grants that fund this research and development require the academic institutions to direct revenues back into research and development efforts. *See also* Alan Dove, *When Science Rides the MTA*, 110 J. CLINICAL INVESTIGATION 425, 425 (2002), *available at* www.jci.org/articles/view/16546/pdf (reflecting that "the commercialization of academic science, particularly biomedical research, has provided a significant source of new funding and sped medical advances from the laboratory to the clinic.").

34 *Ohio-Based Venture Therapeutics Named Industry Partner*, OHIO STATE UNIV., (June 5, 2014), http://cancer.osu.edu/news-and-media/news/ohio-state-and-university-of-michigan-partner-to-bring-oral-cancer-fighting-patch-to-patients.

35 *See id.* ("This type of collaboration, involving multiple university partners with strong industry support, is increasingly essential to expedite the discovery, development and delivery of more targeted cancer therapies.").

search with industry and government research,[36] furthers this line of reasoning by defending what he calls the "assisted linear model of science and innovation policy."[37] He finds that there is more effective translation of scientific results into downstream marketable products when there is a close nexus between academic institutions, federal agencies, and industry parties.[38] It is also better understood now that "shared innovative activity tends to characterize the early phase of establishment of an industry."[39]

The term "shared innovative activity" is noteworthy. It is a type of collaborative activity, one that requires repeated interactions in order to share innovation responsibility. This is the kind of collaboration that is needed between academic institutions, federal agencies, and industry to continue establishing new fields and deepen understanding of existing ones. Shared innovative activity is also needed to smooth the transition from upstream research to downstream development, especially as academic institutions continue to explore (and at times struggle) with downstream research and development. Yet shared innovative activity is not easy. Shared innovative activity involves detailed research and collaboration agreements that seek to outline expectations of parties and to provide direction in the midst of risk and uncertainty. These agreements can take months, sometimes years, to negotiate and execute. During that negotiation between lawyers, scientists may struggle to gain access to the building blocks they need for a particular project. Among other consequences, long negotiations may lead to the loss of a grant or the window of time for a particular research project closing.

The building blocks of innovation are materials. Scientists must have physical materials, research tools and data, such as plasmids, cell lines, a high-powered microscope, etc., for experimentation. Furthermore, just as the need for shared innovation activity is seemingly on the rise because of the high level of sophistication within current science and technology, the price of materials, research tools, and data is also on the rise. Receiving access to materials, research tools, and data, whether that access is linked to a bigger collaboration or not, in practice requires an executed MTA. As the line between upstream and downstream research blurs and academic institutions more frequently seek to protect their intellectual property rights, access to materials, research tools, and data has become more restricted.[40]

---

[36] *See Human Sciences and Technologies Advanced Research Institute—About Us*, STANFORD UNIVERSITY, http://hstar.stanford.edu/3helix_about_us (last visited Jan. 24, 2015).

[37] Biddle, *supra* note 30, at 246.

[38] *See id.* (explaining that Etzkowitz's "line of reasoning . . . is echoed by many within university administration.").

[39] Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 FORDHAM L. REV. 2237, 2245 (2009) (internal citations omitted).

[40] *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 294 (2003) (explaining "[a]n important consequence of this shift has been an increase in restrictions on the transfer of research tools, even those that are not patented"). For a discussion on the potential erosion of public sector values as a result of academic science becoming more like that of industry science, see John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L. J.

The MTA went from a relatively rare occurrence to an everyday practice in academic institutions' technology transfer offices. It is estimated that large academic institutions each execute thousands of MTAs annually, spending over $100,000 in MTA management costs.[41] Smaller academic institutions report executing hundreds of MTAs annually,[42] with the collective academy spending millions each year for simple management of MTAs.[43]

The traditional MTA comes in various forms today but at the core is a unifying set of terms that lead to a one-time interaction between the parties. The set of terms concern liability, warranties, and use of the transferred material. This is largely due to standardization efforts of the Association for University of Technology Managers ("AUTM"). The AUTM assembled a special interest group that discussed MTAs with the National Institutes of Health ("NIH").[44] An internal committee of this project produced the Uniform Biological Materials Transfer Agreement ("UBMTA"), and although there are hundreds of signatories, a recent AUTM MTA survey found that the UBMTA is not in widespread use.[45] Instead, academic institutions and government agencies are using their own variations of the UBMTA.[46] Some commentators think that the delays surrounding MTAs are because of their sheer complexity and volume and because the "goldilocks" standard MTA has not yet been developed. This has resulted in calls for more standardization.

This next Part will briefly trace the historical roots of the MTA, identify the form and function of the traditional MTA today, and discuss the recent calls for standardization efforts in more detail. Ultimately, I argue that another standardized MTA is not what the market needs. Instead, parties need to better identify whether their transfer requires a traditional MTA or whether the transfer requires a modern version of the MTA, one that plans for repeated interactions between the parties.

A. The Rise of Academic Science

The long-standing rhetoric surrounding universities is that they are secluded high above the world in ivory towers, divorced from the reality of the world and the

---

101, 110-11 (2001).

41 *See* Bentley, *supra* note 13, at *5.

42 *See, e.g.*, *MTAs*, EMORY U. OFFICE OF TECHNOLOGY TRANSFER (2015), http://ott.emory.edu/about/statistics/mta.html (illustrating steady growth of executed MTAs from 2005-2013, with approximately 700 in 2013).

43 *See* Bentley, *supra* note 13, at *5. It is also likely that these numbers are greatly underestimated as many technology transfer offices and industry specialists do not track or report their respective MTA numbers and practices. *See* Philip Mirowski, *Livin' with the MTA*, 46 MINERVA 317, 323-24 (2008).

44 NATIONAL INSTS. OF HEALTH, UNIFORM BIOLOGICAL MATERIALS TRANSFER AGREEMENT (1995), *available at* http://www.autm.net/Content/NavigationMenu/Members/UBMTA/default.htm (search "Uniform Biological Materials Transfer Agreement").

45 ASS'N OF UNIV. TECH. MANAGERS, AUTM 2011 MATERIAL TRANSFER AGREEMENT SURVEY REPORT (2011), *available at* http://www.autm.net/AUTMMain/media/Resources/Documents/MTASURVEYFINAL.pdf.

46 *See* Rai & Eisenburg, *supra* note 40, at 306.

market.[47] In academic science terms, the suggestion is that universities are more concerned about upstream research than how that research is applied or utilized in the downstream process. The recent downstream success of academic institutions like Columbia and NYU demonstrates this this is no longer true (if it ever was).

Notably, however, organized discussions about MTAs did not occur until the early 1990s. It was then that a special interest group was put together by the AUTM to think about standardization of MTAs for the first time. Conversely, there are oft-repeated stories about how materials were once shared informally, with no written agreement, between noncommercial and commercial scientists.[48] What caused this dramatic change in how materials are shared?

One reason for the sudden appearance of MTAs is increased financial support and patenting in academic science. After World War II there was a rush to support academic science.[49] The time period of 1950-1975 saw rapid increases in federal expenditures for research and development, and, concomitantly, higher numbers of patents issued to universities.[50] Federal expenditures supporting research and development made up 55% of all university research spending in 1953 and 73% in 1966.[51] In actual dollars, universities received approximately $273 million in 1953, accounting for 5.3% of total national research and development expenditures.[52] This percentage rose to 7.9% in 1965 and to 10% in 1970.[53]

In the 1950s and 1960s there were roughly fewer than 100 patents issued per year to universities, yet in 1972 there were over 200 patents awarded to universities.[54] By 1975, that number was at 300.[55] This means that between the mid-1960s

---

47 *See* Lee, *supra* note 29, at 7-8; Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1374 (2006) ("Universities have a reputation for being isolated ivory towers"); C.L. Max Nikias, Exec. Vice President and Provost, Univ. S. Cal., Beyond the Ivory Towers: On Tomorrow's American Research University, Thirty-First Annual Earl V. Pullias Lecture (Jan. 22, 2009), *available a*t http://www.president.usc.edu/speeches/beyond-the-ivory-towers-on-tomorrows-american-research-university/ ("We face increasing cynicism about the academy. Elite research universities have been criticized as being too divorced from the concerns of ordinary women and men, too insular, too wealthy, too inefficient, too expensive, too naïve about the realities of life beyond the ivory tower."). *See also* Steven Shapin, *The Ivory Tower: The History of a Figure of Speech and Its Cultural Uses*, 45 BRIT. J. HIST. SCI. 1, 1-27 (Mar. 2012), *available at* http://www.fas.harvard.edu/~hsdept/bios/docs/shapin_Ivory_Tower_BJHS.pdf (providing the historical origin of the phrase "ivory tower" and how it has changed over the years).

48 *See, e.g.*, LaMattina, *supra* note 31, at 44 (former Pfizer researcher explaining that "[m]any years ago, MTAs were unheard of").

49 *See* ELIZABETH POPP BERMAN, CREATING THE MARKET UNIVERSITY: HOW ACADEMIC SCIENCE BECAME AN ECONOMIC ENGINE 19 (2012) ("University research was a modest, small-scale endeavor until the Manhattan Project demonstrated the power of science and, in the process, transformed the way it was organized.").

50 *See id*. at 35-36.

51 *Id*. at 37.

52 *Id*.

53 *Id*.

54 *Id*. at 100.

55 *Id*.

and mid-1970s the number of issued academic patents tripled.[56] During the mid-1970s there were pushes from private industry and federal agencies to support research and the collaboration between academic science and industry science.[57] This caused new tension. I argue more collaboration and shared innovative activity is a worthwhile goal, but that we must work to decrease tension that occurs when combining industry and academic science.

One of the reasons for this tension when combining academia and industry in the 1970s is the same reason there is tension today: there are inconsistent missions. There is an inconsistent mission in industry versus academia and to make matters more complicated, there is also an inconsistent mission in academia itself.

As identified and described by technology transfer specialists, there are multiple missions in academic science such as the preservation and dissemination of ideas and the generation and output of new discoveries.[58] At times, these missions seem to conflict, making it difficult to maintain consistency in the ultimate objective(s) of academic institutions.[59] Moreover, the mission of an academic institution may not also be the same as those of its faculty. Ultimately, the rewarding nature of the patent system—disclosure of an invention in a particular way resulting in the grant of twenty years of exclusive rights to the invention—seems largely incongruent with ensuring that the public has equal and affordable access to output. Interviews I have conducted, as well as those by other commentators, confirm that "[c]ompanies [continue to] complain that universities do not understand business and suffer from a cultural schizophrenia about whether they are businesses or academic institutions."[60]

Compare the at-time competing missions of academic institutions to that of industry: profit maximization. Although industry scientists may work in laboratories that collaborate with large numbers of academic scientists, their end goal of producing a successful product or process makes for a different work environment than that of an academic institution. Academic scientists operate under a somewhat open environment with research results being published and presented, whereas industry scientists are much more likely to keep their research and the results secret until at least the patenting process is well on its way.[61] As one patent scholar and former academic scientist notes, "it is more difficult to stabilize and enforce norms of sharing

---

56 *See id.* at 95 (explaining that "the number of patents issued to universities roughly tripled between the mid-1960s and the mid-1970s.").

57 *Id*.

58 *See* Council on Gov't Relations, *Material Transfers in Academia: 20 Questions and Answers* (Sept. 2003), http://www.ucop.edu/research-policy-analysis-coordination/_files/Materials_Transfer_in_Academia.pdf.

59 *Id*.

60 Mirowski, *supra* note 43, at 328 (internal citations omitted).

61 *See* Strandburg, *supra* note 39, at 2260 (suggesting that "the social benefits of research tool sharing are less clear when industry scientists are involved since they are more likely to keep their research results secret").

in a community consisting of both academic and industry scientists than in a more homogenous academic research community."[62]

Stabilizing and enforcing norms in a heterogeneous science community was made more difficult when Senator Bayh in 1980 "managed to squeak" the University and Small Business Patent Procedures Act through Congress.[63] Commonly referred to as the Bayh-Dole Act, the Act has profoundly impacted academic science.[64] The Bayh-Dole Act affirmed that universities are allowed to patent any resulting inventions if several conditions are met.[65] These conditions include the university's disclosure to the federal government of an invention "within a reasonable time,"[66] as well as informing the federal government of any intent to obtain a patent[67] and providing updates when requested to do so.[68] Also, "the university must retain title," "share licensing proceeds with the inventors," and "the balance of licensing income must be used to support 'scientific research or education.'"[69] With this new legislation, among other things, Congress aimed to encourage collaboration between non-profit entities, including academic institutions, and industry.[70] Yet with increased funding and academic and industry patenting, there is more secrecy and competition.[71] When academic and industry scientists come together to share or transfer technology, including materials, research tools, and data, the clash of internal academic goals and industry goals is apparent.[72]

Moreover, the tension between university research and industry research is not new, but the norm is shifting so that universities in particular disciplines are more consistently competing with industry partners. This means that academic and industry scientists may be engaged in similar research and development efforts. As a former president of Duke remarked, "universities should do all that is reasonably possible to earn returns on inventions, and should not be timid in making prudent business arrangements to assure the largest fair return."[73]

---

62 *See id*.

63 Ritchie de Larena, *supra* note 47, at 1375 n.5.

64 *See* BERMAN, *supra* note 49, at 113-115 (discussing factors leading to the explosion of academic patenting and naming one of the critical three as the passing of the Bayh-Dole Act).

65 *See* Ritchie de Larena, *supra* note 47, at 1375.

66 35 U.S.C. § 202(c)(1) (2000).

67 35 U.S.C. § 202(c)(3).

68 Ritchie de Larena, *supra* note 47, at 1375.

69 *Id*. (citations omitted).

70 *Id.*

71 Secrecy must be maintained until at least a patent application is filed. This is truer under today's patent system than ever before. As of March 16, 2013, we are now under a first-to-file regime, as opposed to a first-to-invent system, making secrecy until the patent application is filed key. *See America Invents Act*, Pub. L. No. 112-29 (2011).

72 *See* John E. Tyler III, *Advancing University Innovation: More Must Be Expected—More Must Be Done*, 10 MINN J.L. SCI. & TECH. 143, 158 (2009).

73 Lee, *supra* note 29, at 39 (citing Terry Sanford, *The University and Technology: New Paths and New Perspectives*, 1 in THE LAW OF BUSINESS AND LICENSING: LICENSING IN THE 1980S 1, 1-67 (Robert Goldscheider and Tom Arnold eds., 1989)).

This cultural change is another reason why there was a sudden increase in the use of MTAs.[74] Virtually every transfer is accompanied by a transfer agreement. On average, a technology transfer office sees two or more MTA requests, whether outgoing or incoming, per day, with at least "annual compounded growth rates of incoming MTAs of somewhere between 6% and 15%, with no end in sight."[75]

With the aim of protecting discoveries in industry, academic science, and government science, every material is a piece in the puzzle that could be the last one needed to create that blockbuster patented technology. Conversely, due to the value of patentable technology (and therefore liability in a patent infringement suit), as well as the increasing volatility and sophistication of technology (for example, tissue samples from animals and humans infected with MERS or Ebola or tools to build the latest nuclear weapons), every material has much more liability attached to it. This increases the risk of transfer and the level of attention paid to the agreements that accompany these high-risk transfers.

B. The Traditional MTA and the Efforts to Standardize

In the past 30 years there have been repeated calls for and attempts made to standardize MTAs. Among others, the NIH, AUTM, former Science Commons (currently a part of the Creative Commons), a non-profit plasmid bank at addgene.com, the Scripps Research Institution, and individual universities like Vanderbilt have answered calls for standardization with their respective MTAs or systems for streamlining the process.[76] Although there are standardized MTAs available for use, a 2011 AUTM MTA Report shows that the noncommercial entities that made the most vocal calls for a standardized option, that is, universities, teaching hospitals, and non-profit research laboratories, are nevertheless not routinely using the standardized options.[77]

---

[74] *See* Richard Li-Dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251, 253 (2008) (explaining that "[t]he prospect of having to apply for patents is causing an increasing number of researchers to keep their excellent ideas secret at least until the patent application is filed.").

[75] Mirowski, *supra* note 43, at 325 (Mirowski believes that these numbers "are almost certainly underestimates").

[76] *See infra* Part I.B and accompanying notes.

[77] *See supra* note 45, at 11(finding that for academic-to-academic transfers, only a minority of institutions used standardized agreements made available by the National Institutes of Health"). *See also* Rai & Eisenberg, *supra* note 40, at 305-06 (explaining that the UBMTA has enjoyed "limited suc-

Despite this nonuse, at least part of the academic institution intellectual property community would like to see another standardized option; in particular, one that is designed for industry-to-academic institution exchange. Yet efforts to draft a standardized industry-to-academic institution MTA continuously are "impeded by the varying positions among companies."[78] Perhaps an opportunity exists for a scholar, one not tied to a particular technology transfer office or to an industry partner, to draft an unbiased standardized agreement for use in the industry-to-academic institution transfers. But why would a standardized agreement work any better now than it has in the past, especially when the easier transfers from academic-to-academic institutions are not executed using the currently available standardized options?

Industry counsel and technology transfer counsel know the risks of transfers. They know how to draft MTAs. The lack of standardized options is not the problem. Instead, there is a disconnect regarding the mission of the MTA that is similar to the disconnect in the sometimes dueling missions of academia. This lack of synergy is causing much of the delay in executing MTAs.

Lawyers and licensing specialists are not starting with the same outcome in mind. Does the MTA need to simply serve as a record of the transfer of a material and outline of respective liabilities? Or is the MTA a stepping-stone towards a larger collaboration involving repeated interactions?

MTAs vary widely between academic institutions and industry partners. Yet the basic term sheet is largely similar—identifying the parties subject to the agreement, the material, the length of time the material is needed, and the recipient's intended use of the material, etc. This front-page similarity leads to the failed identification of the two different functions and corresponding types of MTA: the traditional MTA and the modern MTA. The traditional MTA is currently in high use in technology transfer offices. After the Bayh-Dole Act was passed in 1980 and as biomedicine continued to thrive, scientists became increasingly vocal in the 1990s that the progress of their research was slowed down because of lengthy MTA negotiations.

An empirical study published in 2002 found that over 47% of academic geneticists who had asked "other faculty for additional information, data, or materials regarding *published* research reported that at least one of their requests had been denied in the preceding three years."[79] This is a significant increase from the

---

cess" and that academic institutions "substitute . . . their own form agreement[s] for the UBMTA").

78 *See* Rai & Eisenberg, *supra* note 40, at 305-06 (discussing one industry-to-academic institution initiative that is "classified according to the degree of exclusivity needed by the provider company relevant to a particular material" and that "[l]ower-risk exchanges could then be standardized, and higher risk exchanges could occur according to agreed-upon general principles, with latitude to negotiate.").

79 Eric G. Campbell et al., *Data Withholding in Academic Genetics: Data From a National Survey*, 287 JAMA 473, 473 (2002), *available at* http://www.ncbi.nlm.nih.gov/pubmed/11798369 (emphasis added).

previously reported number in the mid-1990s, which was just over 34%.[80] The authors of the study explain the cause may be that the "material transfer agreements have become so complex and so demanding that they inhibit sharing."[81] Other studies show the delays and forced abandonment of projects resulting from prolonged or failed MTA negotiations.

For example, in studying MTAs the Science Commons reported different numbers than the 2011 AUTM MTA Report. According to the Science Commons, in the academic-to-academic context, studies show estimated delays of transfer range over 1 month for 11% to 16% of MTA requests "to estimates that there are routine delays of over 6 months for 20% of requests and over 2 months for 42% of requests."[82] In industry-to-academic transfers, "most observers believe the situation is worse."[83] The Science Commons does not give time estimates for industry-to-academic transfers, but cites the lack of any standardized agreement as a reason why delays are worse. The Science Commons then gives estimates that in the industry-to-academic transfers the denial rates are almost twice that of the academic-to-academic requests (33% compared to 18%).[84]

The 2011 AUTM MTA Report finds that in the academic-to-academic MTAs, 92% are completed in 3 months or less, while in the industry-to-academic MTA requests, 79% are completed in 3 months or less.[85] In terms of failed negotiations, transfer technology specialists from UC-Davis have estimated that in the year 2007, 10-25% of incoming materials from industry were never executed.[86] The UC-Davis team did not report how long the successfully negotiated transfers took to negotiate and execute.

Certainly while the numbers vary from study to study, it is nevertheless clear that the negotiation process of MTAs, especially when it is between industry and academic institutions, takes a period of time that may be detrimental to specific research projects due to grant timelines and the general racing pace of research and technology. Studies further show that outright denials of requests even for published research are increasing, as is the "abandonment of 'promising research projects' because materials are not received."[87]

Academic institutions argue that the MTAs causing these transfer delays or denials are agreements that call for a indemnification of laboratory accidents or patent

---

80 *Id*. at 478.

81 *Id*. at 479.

82 *Empirical Data About Materials Transfer Problems*, SCIENCE COMMONS, sciencecommons.org/projects/licensing/empirical-data-about-materials-transfer (last visited Apr. 12, 2016).

83 *Id*.

84 *Id.*

85 *Supra* note 45, at 19.

86 *See* ALAN B. BENNETT ET AL., INTELL. PROP. MGMT. IN HEALTH AND AGRIC. INNOVATION: A HANDBOOK OF BEST PRACTICES 697 (A Krattiger et al. eds., 2007), *available at* www.ipHandbook.org.

87 *Supra* note 82.

infringement lawsuits resulting from use of the transferred material, cash payment, a reach-through royalty on the sales of any developed product, a reach-through equity share of any company developed from technology developed using the transfer materials, a grant-back provision allowing the transferor an option to license any technology arising through the use of the materials, a provision prohibiting the sharing of the materials with other universities or private firms, and even pre-publication editorial review of any research results.[88] These contested terms are discussed with suggested workaround solutions in Part III.

One of the reasons why these terms are frequently contested is that the traditional MTA does not contain many of these more controversial terms. So when they are in the modern MTA, which is seeking to build a relationship, these terms seem out of place and inappropriate. The reason why these terms are not in the traditional MTA is perhaps due most recently to the National Institutes of Health (NIH). As a response to the increasingly vocal complaints of the complexity and volume of MTAs, the NIH and universities collaborated in 1995 to develop a standard material transfer agreement for the transfer of biological materials (for example, plasmids, compounds, antibodies, and peptides). This standard agreement, the "Uniform Biological Material Transfer Agreement," or UBMTA, has over 500 universities and colleges that are signatories.[89]

The UBMTA is the most widely recognized pre-negotiated, standardized MTA. However, as noted above, the UBMTA has failed to garner use by many academic institutions and non-profits. That said, it is representative of what I am calling here the "traditional MTA." The terms and conditions of the UBMTA are simple and short. Most notably, ownership of the material stays with the Provider.[90] If the Recipient of the material creates any substances or products that contain or incorporate the material that results in a modification of the material, the Recipient retains that ownership. The UBMTA directs the parties to clear ownership status of the material with these two clauses.

The "use" clause of the UMBTA states that the Recipient of the materials agrees to only use the transferred material "for teaching and academic research purposes" and only in the Recipient Scientist's lab.[91] The Recipient also may not transfer the material to anyone else without written permission, and if the Recipient wants to use the material in clinical trials or for other diagnostic purposes involving human subjects, the Recipient has to get prior written consent of the Provider.[92] Fol-

---

88 Rai & Eisenberg, *supra* note 40, at 294-95. *See also supra* note 58 (explaining that MTAs have problematic terms that "restrict academic freedom," "assert excessive rights of ownership," and "ask for inappropriate indemnification by the university.").

89 *Master UBMTA Agreements* Signatories, ASS'N OF UNIV. TECH. MANAGERS, http://www.autm.net/resources-surveys/material-transfer-agreements/uniform-biological-material-transfer-agreement/master-ubmta-agreement-signatories/ (last visited Apr. 4, 2016).

90 *Id.*

91 *Id.*

92 *Id.*

lowing the clauses regarding the ownership, use, and further transfer of the material, the UBMTA contains a standard warranty disclaimer. And finally, it contains a liability clause under which the Recipient assumes all liability for damages arising "from its use, storage or disposal of the Material" and requires the Recipient to acknowledge the transfer of the material in an attribution clause in all publications using the material.[93]

The UBMTA is completely pre-negotiated, with signatories only needing to execute the 2-page UBMTA implementing letter when they want to transfer materials. The UBMTA Implementing Letter serves to record materials or tools transferred between universities, and the only place where the terms might vary is if there is a "transmittal fee" for the materials.[94] This is not mandatory, but if the parties choose to include one then the Recipient can "reimburse the Provider for preparation and distribution costs."[95] The opening paragraph of the 2-page implementing letter states:

> The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST . . . and the RECIPIENT SCIENTIST . . . to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") March 8, 1995, and to certify that the recipient . . . organization has accepted and signed an unmodified copy of the UBMTA. The recipient organization's Authorized Official also will sign this letter if the recipient scientist is not authorized to certify on behalf of the recipient organization. The recipient scientist (and the Authorized Official of Recipient, if necessary) should sign both copies of this letter and return one signed copy to the provider. The provider scientist will forward the material to the recipient scientist upon receipt of the signed copy from the recipient organization.[96]

This agreement contemplates that the parties are going to transfer the material, that the parties will conform to their promises, and that the parties will not use this agreement for any further interaction. There is no reach-through agreement, no licensing options, and no shared responsibilities for publication or patent applications. Also, if a modification of the material transferred does occur and needs a different ownership term, for example, the UBMTA simply instructs the two parties that they may negotiate for that outside of the UBMTA.[97] The only standard set by the UBMTA regarding future collaboration is that if the Recipient wants to use or license the material or modification for commercial purposes, the Recipient must "negotiate in good faith" with the Provider for this separate right.[98] This does not so much contemplate collaboration, but the expectation that the Recipient will ask permission from the Provider for commercial use rights.

---

93 *Id.*

94 Uniform Biological Materials Transfer Agreement (UBMTA), ASS'N OF UNIV. TECH. MANAGERS, *http://www.autm.net/autm-info/about-tech-transfer/about-technology-transfer/technology-transfer-resources/ubmta/* (last visited Apr. 4, 2016) (click "Download UBMTA Implementing Letter").

95 *Id.*

96 *Id.*

97 *See id.*

98 *Id.*

There are many situations that might occur outside the proper scope of the UBMTA. For example, if the material transfer is requested for a research project that has any ties to a third party, and many do, the UBMTA is generally inappropriate because the UBMTA was pre-negotiated without the third party's involvement. The 2011 AUTM MTA Report found that out of 83 survey respondents reporting on academic-to-academic transfers (understood to be the least difficult kind of transfer), "only 31 percent reported frequently receiving the uniform biological material transfer agreement as the proposed agreement."[99] Conversely, 61% reported frequently using their own agreement.[100]

The NIH itself provides other standardized options for academic-to-academic transfers, as well as transfers involving industry partners. The NIH also published guidelines in 1999 to aid biomedical transfers between NIH-funded parties and others.[101] And although those that receive funding from the NIH are strongly encouraged to use the NIH forms, the MTA Report showed that only 15% of survey respondents frequently use the NIH Simple Letter Agreement.[102] The NIH describes its Simple Letter of Agreement (SLA) as one that may be "[u]sed to transfer vectors, plasmids, compounds, antibodies, peptides, etc."[103] This means that the SLA covers many of the same materials that the UBMTA does. As with the UBMTA, the SLA has specific representations that the Recipient makes when using this agreement, such as that the material transferred "will be used for teaching or not-for-profit research purposes only," that the material "will not be further distributed to others without the Provider's written consent," and that the Recipient "agrees to acknowledge the source of the material in any publications reporting use of it."[104]

The SLA also expressly disclaims on the Provider's behalf that any representations or warranties come with the Material, and states that the "Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider."[105] This is substantially similar to the clauses in the UBMTA. But the NIH also provides templates to use for the transfer of human materials, the Human Materials – Material Transfer Agreement (HM-MTA), and for transfers of organisms such as mice and flies, the Material Transfer Agreement for the Transfer of Organisms (MTA-TO).[106] Both the HM-

---

99 *Supra* note 45, at 11.

100 *Id*. at 16.

101 *See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Resources: Final Notice*, 64 Fed. Reg. 72090 (Dec. 23, 1999).

102 *Id*.

103 *Material Transfer Agreements*, TECH. TRANSFER CTR. OF THE NAT'L CANCER INST., https://ttc.nci.nih.gov/forms/mta.php (last visited Sept. 1, 2014).

104 *See id*. (click "Simple Letter of Agreement (SLA)").

105 *Id*.

106 *See id*. (click "Human Materials - Material Transfer Agreement (HM-MTA)" or "Material Transfer Agreement for the Transfer of Organisms (MTA-TO)").

MTA and the MTA-TO are used exclusively for the transfer of materials between academic institutions or non-profit organizations.

As stated above, despite the ready availability of standardized MTAs, academic institutions frequently use their own agreements. This is likely for several reasons, but mainly because the underlying grant that supported the creation of the material to be transferred has strings attached to future transfers. And certainly, if the grant is from an industry partner, there will be transfer restrictions regardless of its use, whether it is for upstream or downstream transfer. The academic institutions' standardized MTAs also do not support further downstream use or collaboration.

Consequently, the pre-negotiated, noncommercial-only and static nature of the standardized UBMTA, SLA, HM-MTA, and MTA-TO makes them unsuitable for many requests. That is not to say that these agreements do not have their use. When materials need to be exchanged quickly, like with the MERS example above, these standardized options set easy bright lines for parties to follow and are suitable for transfers between academic institutions.

Perhaps one of the best examples of a standard one-time interaction with a near automatic MTA is WiCell, "the global leader in the banking, cytogenetic testing and distribution of stem cell lines."[107] WiCell is a subsidiary of WARF, the Wisconsin Alumni Research Foundation, and was selected by the NIH to host the National Stem Cell Bank.[108]

If a researcher wants a particular type of stem cell line, she merely has to point and click on a website to put the stem cell line into her online shopping basket. The researcher then goes through checkout, which requires registration and an accompanying MTA depending on the line selected. If one is from the Wisconsin International Stem Cell Bank, which is operated by WiCell, a simple MTA is required upfront.[109] The MTA used is the SLA, and represents the traditional MTA at its best. Researchers are not going to collaborate with WiCell. Researchers just want access to the stem cell lines housed with WiCell. The only catch is that it is only a near-automatic system if the request from WiCell is for noncommercial purposes. If there is any potential for downstream use, this takes the request out of the standardized form and opens up more tailored negotiations.

As for academic institutions specifically, while university technology office staff understands that "academic investigators often find MTAs burdensome," they are steadfast in asserting that MTAs must be used to help protect their institution's interests.[110] Technology transfer specialists opine that "[t]his protection is important

---

[107] WICELL, http://www.wicell.org (last visited Jan. 24, 2015) .

[108] *See id*.

[109] *Request for iPS Wisconsin Materials*, WICELL, (2006), http://www.wicell.org/media/WiCellAgreements/WiCell-iPS-MTA.pdf.

[110] James Henderson, *Commentary: Counterpoint: MTAs as a Practical Necessity*, 22 NATURE BIOTECHNOLOGY 722, 722 (2007), *available at* www.nature.com/nbt/journal/v25/n7/full/nbt0707-

to the university, investigators and laboratory personnel, and seeking this protection is driving the increased number of MTAs."[111] Research also shows that it is academic institutions that are driving the increased numbers of MTA requests.[112]

C. Mechanics of the Traditional MTA

The following discussion will highlight specific MTA practices at academic institutions across the nation. These practices will be compared to the UBMTA to fully understand what academic institutions often include that the UBMTA does not. As stated above, even though an overwhelming number of academic institutions are signatories of the UBMTA, they more often use their own version of the traditional MTA. Take for example, the Technology Transfer System of the University of California ("UC"), which has existed in some capacity for over 40 years and is quite expansive. The UC Technology Transfer System is made up of, and responsibility is shared, by the UC's Office of the President, 10 UC campus technology offices, and the Lawrence Berkeley National Laboratory.[113] Like the missions of universities back in the 1930s and 1940s, the UC focuses on the public's access to any resulting innovation, stating that "[o]ne significant aspect of the University of California's public service mission is to ensure that the results of its research are made available for public use and benefit."[114]

Unlike many other academic institutions, the UC Technology Transfer Program publishes annual Technology Commercialization Reports, with the 2013 Report detailing the number of inventor disclosures (1,727), new license agreements executed (427), and new companies launched (71).[115] The 2013 Report also shows that in 2013, the UC filed 1,832 patent applications, was issued 395 U.S. patents, and had 2,328 active licenses.[116] And, finally, the 2013 Report shows that its royalty and fee income was $106 million.[117]

The UC Technology Transfer Program has many personnel that are focused on MTAs. In the UC-Davis Office alone, for example, there are two staff members who are "Senior MTA Analyst[s]," two more that are "MTA Analyst[s]" and an "MTA and Intellectual Property Analyst."[118] There is one more spot listed on the

722.html.

111 *Id*.

112 Mirowski, *supra* note 43, at 325-26 ("It is one thing to blame the rise in MTAs upon rapacious corporations and their crafty legal departments, but it is quite another to acknowledge that the university sector has been doing more and more of this to itself.").

113 *Ideas, Inventions, Impact, Technology Commercialization Report*, U. OF CA. (2013), *available at* http://www.ucop.edu/innovation-alliances-services/_files/ott/genresources/documents/IASRptFY13.pdf.

114 *Supra* note 58.

115 *Supra* note 113, at 3.

116 *Id*. at 19-22.

117 *Id*.

118 *Innovation Access*, UC-DAVIS, OFFICE OF RESEARCH, http://research.ucdavis.edu/contact-us/innovationaccess/ (last visited Sept. 1, 2014) (directory showing MTA Specialist positions).

website for a MTA Analyst that is "In Recruitment."[119] This is in addition to each science-heavy college, such as the College of Biological Sciences and College of Engineering, having its own designated Intellectual Property Officer.[120]

The practice of the UC system is that before "proprietary or valuable material changes hands," a MTA should be executed between the sponsor and receiving party.[121] Each technology transfer office is tasked to help its respective faculty members and researchers negotiate and execute these agreements.[122] There is a standard procedure in place at each individual UC technology transfer office. This procedure is not consistent as to the precise intake forms from campus to campus, although generally it is consistent in that the faculty member, depending on whether it is an outgoing material transfer or an incoming material transfer, fills out a transfer form and submits it to the office for its review.

In the first part of the UC MTA information gathering forms, the UC campus-specific forms look very similar to the UBMTA. The main purpose of these intake forms is to gather the proper recordation information. These forms also ask whether derivatives or modifications of the material will be made and inquire about the extent of possible third party interaction with the material.[123] This includes whether third party material will be added to the incoming material, whether there is third party funding for this material, and what interest there is by the principal investigator at this outside organization, if any. Unlike the previously discussed standardized options, these forms allow for upfront understanding of potential third-party ties to the particular material.

From these intake forms, the respective UC technology transfer office has the basic information and likely just needs to add a few provisions. In the UC-Irvine MTA Agreement covering outgoing biological materials, presumably used when the receiving institution is not an implementing member of the UBMTA or when there is a third party interest at stake and so the UBMTA form is not an option, the UC-Irvine Agreement states that the following conditions must be agreed to prior to the transfer of the materials:

> [T]he Biological Materials will be used only in scientific research;
>
> [T]he Biological Materials will be used with caution and prudence in any experimental work and that the Biological Materials will not be used on any human subjects;

---

119 *Id.*

120 *Id.*

121 *See, e.g.*, *Research Materials*, UC-IRVINE, OFFICE OF TECH. ALLIANCES, ota.uci.edu/industry-resources/research-materials.html (last visited Apr. 3, 2016).

122 *Id.*

123 UC-Irvine specifically asks "Do you plan to use third party materials that were brought into UCI in your research with the Material(s)?" and "Do you have a financial interest in the outside institution (income, consulting, gift, stock ownership or management position)?" *Id.*

> Recipient Institution will bear all risk to Recipient Investigator and to others resulting from use of the Biological Materials;
>
> Recipient Institution will defend, indemnify and hold harmless The Regents for all claims, losses and expenses resulting from your use of the Biological Materials;
>
> Recipient Investigator and Institution will not allow the Biological Materials to be transferred to any other party or use them for commercial purposes without the express written consent of The Regents;
>
> Recipient Investigator and Institution will not allow the Biological Materials to be transferred to any other party or use them for commercial purposes without the express written consent of The Regents;
>
> The University of California will be acknowledged in any publications resulting from your work with the Biological Materials and the UCI Investigator will be given credit in such publications, as scientifically appropriate; and
>
> Recipient Investigator will inform the UCI Investigator of experimental results obtained from using the Biological Materials.[124]

Like the UBMTA and NIH forms, the UC-Irvine standardized MTA adds in the typical disclaimer of express and implied warranties, and, further, a sentence adding that "The Regents makes no representation and provides no warranty that the use of the material will not infringe any patent or other proprietary right."[125] The remainder of the UC-Irvine standardized MTA agreement is a clause stating that there is no license is granted or implied in the MTA.[126]

Overall, the UC system wants more protection than the UBMTA and NIH forms give it in regards to indemnification and rights to the results of research conducted using the transferred material. This UC-Irvine MTA wants the Recipient to not only take responsibility for its own use of the material, but also to completely "defend, indemnify and hold harmless" the UC.[127] It is noteworthy that although academic institutions complain that industry partners want too much in terms of indemnification, as will be discussed in the next section, the UC system makes this same request of others.

The UC-Irvine MTA also goes beyond the UBMTA and the NIH forms when it states that the Recipient "will inform" the UC scientist of its research results using the material. The Recipient's research must be academic in nature, but there is no reciprocal clause stating that the UC-Irvine must use the Recipient's research results for noncommercial purposes. So instead of the right to potentially have access to or use of any research or resulting substance or product that is made using the material

---

[124] *Outgoing Material Transfer*, UC-IRVINE OFFICE OF TECH. ALLIANCES, http://ota.uci.edu/industry-resources/outgoing-material-transfer.html (last visited Apr. 4, 2016).

[125] *Id.*

[126] *Id.*

[127] *Id.*

through a reach-through royalty or option right, the UC system wants to obtain the research results and use them how it seems fit.

The UC-Irvine MTA may be interpreted as sending mixed signals and exemplary of the dueling missions within academia. The UC system focuses on making its research available for the public use and benefit, yet it also it puts restrictions on others using its materials. As the UC system's annual technology commercialization reports demonstrate, the UC system does want to make use of the patent system, bring products to the market, and create new companies that will then subsequently compete with the UC on the market.

A significantly smaller public institution than that of the UC, but one that nevertheless has a very active technology transfer practice is Georgia Technology Institute ("Georgia Tech"). At Georgia Tech, the Georgia Tech Research Corporation (GTRC), set up as a state-chartered 501(c)(3) not-for-profit corporation, serves as the governing body that protects and manages all intellectual property created at Georgia Tech.[128] The GTRC is just one of approximately 100 separate entities connected to state institutions that either completely own or perhaps just license intellectual property of those respective state institutions.[129] The GTRC does a variety of business and contracting activities for Georgia Tech, but it is the Office of Industry Engagement within the GTRC that "is responsible for the protection, licensing, and management of Georgia Tech's intellectual property portfolio."[130]

In 2012, the Office of Industry Engagement reported that it spent $730 million on research expenditures, had 407 invention disclosures filed, received 79 new U.S. patents, executed 89 new licenses and/or license options (bringing the total active licenses to 620), and facilitated the formation of 12 new startups.[131] Despite its different organizational structure from the UC system, Georgia Tech employs a similar process to be followed by faculty or researchers who want to send or receive materials to support research. There is an Outgoing Material Transfer initiation form and an Incoming Material Transfer initiation form.[132]

The questions on the Incoming Initiation Form focus on third-party involvement, asking "[w]ill the Material be used with any materials you have received or will receive from any other institution, corporation, or business entity" and "[w]ill the Material be used in collaboration with any non-GIT parties?"[133] The Georgia

---

[128] *About GTRC*, GA. TECH RESEARCH CORP., www.gtrc.gatech.edu/about-us/ (last visited Apr. 3, 2016).

[129] *Id.* Georgia Tech further explains that "[t]hese foundations are organized primarily to permit their host universities to operate research programs by minimizing the impact of restrictive state contracting and financial procedures." *Id.*

[130] *Related Offices*, GA. TECH RESEARCH CORP., www.gtrc.gatech.edu/related-offices (last visited June 28, 2015).

[131] *Economic Impact Data*, GA. TECH RESEARCH CORP., industry.gatech.edu/about/impact/ (last visited June 28, 2015).

[132] *Id.*

[133] Incoming Material Transfer Initiation Form, GA. TECH RESEARCH CORP.,

Tech Incoming form does get a bit more detailed, however, specifically wanting to know if the Material being received by the Georgia Tech researcher is human embryonic stem cells or recombinant DNA, both biological materials that are infamously covered by university patents.[134] It also asks whether the Provider requires a MTA, and, if not, the Principal Investigator is able to skip a number of questions and ultimately provide very little detail to the Georgia Tech Office of Industry Engagement.[135]

The Outgoing Initiation Form asks whether the Material being sent from Georgia Tech is "associated with an invention already disclosed to the Office of Innovation and Translational Research."[136] The Outgoing Form also asks the third party question, adding, "Are there other reasons why you believe an MTA is necessary?"[137]

Georgia Tech puts in writing that MTAs are only legally enforceable at Georgia Tech if particular people execute the MTA.[138] This is likely in response to a practice early on where MTAs were "more often than not . . . summarily signed by the researcher in question, without any oversight concerning their provisions."[139] Unlike the UC system, at least UC-Irvine, Georgia Tech does not make its template MTA publicly available.

Private institutions also manage and execute hundreds of MTAs per year. Most private institutions, such as Emory[140] and Columbia,[141] handle them similarly to the UC system and perhaps like Georgia Tech, at least as much as the intake and outtake forms show. Dartmouth is slightly different in that it publicly posts its standardized agreements prior to the transfer, not just its intake or outtake forms.[142]

Dartmouth has three separate Outgoing MTAs: MTA to Nonprofit Institutions, to Industry, and to Industry with a Fee. The MTA with Nonprofit Institutions looks

---

http://industry.gatech.edu/researchers/forms/ (last visited Apr. 4, 2016) (click "Incoming Material Transfer initiation form).

134 *Id.*

135 *Id.*

136 Outgoing Material Transfer Initiation Form, GA. TECH RESEARCH CORP., http://industry.gatech.edu/researchers/forms/ (last visited Apr. 4, 2016) (click "Outgoing Material Transfer initiation form").

137 *Id.*

138 *Material Transfer Agreements*, GA. TECH. SCH. OF LIT., MEDIA, AND COMM., http://lmc.gatech.edu/~hpritchard/3404/MTA2.swf (last visited Apr. 4, 2016).

139 Mirowski, *supra* note 43, at 321.

140 *See Office of Technology Transfer, Research Administration, MTAs*, EMORY UNIV., http://ott.emory.edu/about/statistics/mta.html (last visited Apr. 4, 2016).

141 *See Technology Ventures, Forms + Agreements*, COLUM. UNIV., tech-ventures.columbia.edu/inventors/forms-agreements (last visited June 28, 2015) (using the common Incoming and Outgoing forms to help expedite the information sharing process and get the MTA drafted and executed quickly).

142 *See Technology Transfer Office, Material Transfer Agreements*, DARTMOUTH COLL., www.dartmouth.edu/~tto/mtas.html (last visited Apr. 4, 2016).

similar to the UBMTA and covers biological materials. Ownership stays with Dartmouth, Dartmouth gives no warranties, and the Recipient must hold Dartmouth "harmless from any loss, claim, damage or liability, which may arise from Recipient's use, storage and disposal."[143] This is similar to the UC-Irvine MTA, but it is narrower. The scope of the UC-Irvine MTA indemnification clause is "for all claims, losses and expenses resulting from [the] use of the Biological Materials," whereas the Dartmouth MTA with Nonprofit Institutions is limited to the Recipient's use, storage, and disposal of the transferred material. Note that this still goes beyond the UBMTA that just requires the Recipient to assume all liability for damages arising from "use, storage or disposal of the Material."[144]

The Outgoing MTA to Industry and to Industry with Fee also covers "Biological Material" and both have the same warranty disclaimer.[145] The other provisions are much more carefully, and perhaps warily, drafted. The MTAs state that the Biological Material is "not to be given or made available to any other person (other than those scientists working in collaboration with you), firm, or corporation, but [is] to remain under your immediate and direct control."[146] The next paragraph explains that the Biological Material, or any part of it, is not to be used "in or for the production of products for sale, unless XYZ also agrees that prior to any commercialization of any products or processes derived from or with the use of the Biological Material, XYZ will provide appropriate compensation to Dartmouth in accordance with license or other agreement negotiated in good faith between Dartmouth and XYZ."[147]

The MTAs also make clear that Dartmouth is to retain and/or obtain specific rights, namely, that sharing the Biological Material with "XYZ" does not prohibit Dartmouth from sharing the Biological Material with any other commercial or non-commercial entities. Moreover, that XYZ agrees that if it publishes any results of its research that it must appropriately acknowledge Dartmouth's contribution, "as scientifically appropriate."[148] The MTA for Industry with Fee is substantially identical to a transfer without any fee, but has a one-time payment fee ("the Biological Material is provided to you for a one-time license free of $5000 for internal research and /or evaluation purposes only").[149]

Overall, the Dartmouth forms are not as far-reaching as the UC-Irvine MTA with its indemnification or requirement that it be informed of research results, although it contains more projections and restrictions than the UBMTA. These forms are also more detailed with respect to what Dartmouth can do with the material; namely, that it can continue to share it with others for commercial or academic re-

---

143 *Id*.
144 *See supra* note 94.
145 *See supra* note 142.
146 *Id*.
147 *Id*.
148 *Id*.
149 *Id*.

search. But like the UBMTA, NIH forms, and UC-Irvine MTAs, these MTA forms set up the expectation that the material will be transferred and the parties will stick to the agreement and not interact again. There is no talk of future agreements or future expectations of potentially working together. This is the essence of the "traditional" MTA: a one-time transfer of materials with no ties going forward.

Lastly, another private university is emerging as a particular leader in the MTA field. Vanderbilt recently launched "MTAShare," an automated and scale-able system that both processes and manages Vanderbilt-specific MTAs.[150] MTAShare uses the standardized UBMTA and the NIH Implementing Letter, and also has a recordation system to help Vanderbilt track its many outgoing and incoming MTAs. With MTAShare, Vanderbilt believes that the MTA transaction time will be reduced, resulting in saved money and less researcher frustration.[151]

This particular system may help in tracking and managing MTA requests, but it is limited in its adaptability and widespread use. The largest impediment is that the UBMTA, the NIH standardized forms, and the similar MTAs of individual academic institutions all assume that the point of the MTA is simply to record a transfer and outline which party has responsibility if something goes wrong with the transfer. These largely standardized MTAs are static contract mechanisms that assume the same underlying purpose.

As shown in the next section, however, there is another purpose of the MTA that underlies many industry MTAs. The modern function of a MTA is more often tailored to support the beginning of a collaborative relationship. This does not mean that every MTA leads to a further collaboration, but there appears to be an expectation that the MTA is not just for recordation purposes, but rather to set the stage for shared innovative activity.

II. The Emergence of the "Modern" MTA

The above section explains that academic institutions experience longer delays and more failed negotiations when the other party is an industry party. In academia, the response to the increasing MTA requests and delays in negotiating MTAs is to standardize. The thought is that standardization will decrease transaction costs, thereby increasing the flow of materials, tools, and data between scientists.

Industry is not taking this approach to increased MTA requests. Instead of standardization, many industry companies are creating more diverse MTAs. This is particularly true in the biotech and pharmaceutical industry. This industry appears to consistently tailor each MTA to the material and its unique potential for collaborative efforts. Accordingly, these MTAs do not look like the UBMTA or the university templates discussed above, although certainly some of the same clauses are

---

[150] *See Benefits of MTAShare*, VAND. UNIV., CTR. FOR TECH. TRANSFER & COMMERCIALIZATION, http://cttc.co/cttc/content/inventors/mtashare/benefits-mtashare (last visited Apr. 3, 2016).

[151] *Id.*

contained within. What is in the modern MTA that is not in the traditional MTA are forward-looking terms that set up the parties for further interactions leading towards shared innovative activity.

When the MTA is between an industry party and a federal agency, the industry partner's aim is to move quickly from a MTA to a CRADA. A CRADA, a Cooperative Research and Development Agreement, allows federal agencies and nongovernment parties to conduct collaborative research together.[152] In a CRADA, each party must make an intellectual contribution.[153] Furthermore, a CRADA allows a federal agency to receive direct funding from private industry in exchange for the private industry being given access to the federal agency's "personnel, facilities, equipment, and expertise to perform the collaborative research."[154] While there are formal steps that a research-oriented federal agency and nongovernmental party must take when moving from the MTA to the CRADA letter of intent proposing a CRADA and finally to an actual CRADA, the CRADA itself has can vary significantly. Each agency tailors the CRADA to meet the parties desired scope and depth of research and collaboration.[155]

If a federal agency is not involved and instead it is just two or more industry parties coming together, there are not the formal steps as seen with the CRADA. The contractual agreements from the beginning of the companies' relationships look more like a licensing agreement that sets the boundaries of the working relationship allowing for joint exploration. Accordingly, a MTA may be contained within a collaboration agreement, or it may be the first official step that is then amended, expanded or simply terminated to make way for the next contractual agreement.

Overall, the MTA is no longer a simple recording device in industry like the traditional MTA is in academia. It is a stepping-stone. The next Part will explore why industry science is moving in this direction. Understanding the scope and objective of industry science, just like with academic science, will better inform relevant actors and commentators why industry partners are shaping the MTAs they way they are right now.

Accordingly, Part A will focus on the increased scope of private industry. Part B will discuss and analyze recent creative "MTA" contracts in industry science, which are not always called MTAs but do involve the transfer or sharing of materials, tools, or data. Once transfer specialists understand the difference between the traditional MTA and modern MTA, they will be better equipped to lead their companies and academic institutions into the future of science: shared innovative activity that succeeds because of interfirm research and collaboration.

---

[152] *How and When to Use a CRADA*, NAT'L INSTS. OF HEALTH, http://www.nimh.nih.gov/labs-at-nimh/collaborations-and-partnerships/cooperative-and-development-research-agreements/how-and-when-to-use-a-crada.shtml (last visited Apr. 3, 2016).

[153] *Id.*

[154] LAMATTINA, *supra* note 31, at 45.

[155] *Id.*

A. Increased Scope of Industry Science

Scientists working in the "discovery" phase are not limited the way noncommercial scientists working in a non-profit laboratory are.[156] There are many for-profit companies, ranging from the small biotechnology firm to the publicly traded pharmaceutical giant that houses thousands of commercial scientists engaged in the discovery phase of research. The amount of commercial scientists working on the upstream phase of research has, like with academic scientists working on the downstream phase of research and development, recently increased.[157]

One way to access this trend is to look at the increase in biotechnology and gene sequence patents. In 1990, fewer than 1,000 biotechnology patents issued. By 1998, the number of biotechnology patents had skyrocketed to 5,977 patents.[158] The number of biotechnology patents declined over the next few years, yet the PTO granted 4,324 in 2004.[159] This number continued to decline slightly, with just under 4,000 biotechnology patents granted by the PTO in 2009.[160]

The numbers worldwide similarly track this rapid increase in biotechnology patents. In 1977, measured by PCT applications, there were just 12 biotechnology patents filed globally.[161] By 2009, this number had increased by over 77,000%, reaching 9,339 patents filed globally in the field of biotechnology.[162] The number of bioscience patents issued in the U.S. has continued to steadily increase every year since 2009.[163]

The trend of more upstream patents, especially in areas like bioscience, is not likely to change, although there is an ongoing debate about the impact that upstream patents might have on the rate of innovation in fields like biotechnology research.[164] The most notable projection of a decline in this area regards funds from the NIH and from risk capital investment.[165] These trends as to increased upstream patents and potentially less funding are indicators that we can expect more competition

---

156 LAMATTINA, *supra* note 31, at 23 (describing the "discovery" phase as one that at pharmaceutical companies includes "early experimentation . . . focused on inventing a compound that has the credentials to justify its worthiness for clinical studies").

157 *See* Wang, *supra* note 74, at 253 (explaining that "breakthroughs in biotechnology and prosperous development in the biotechnology industry" have led to "a large increase in the number of patents granted.").

158 *Id*. at 255 (citing David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1687–1731 (2007)).

159 *Id*.

160 Pugatch et al., *supra* note 19.

161 *Id*. at 29.

162 *Id.*

163 George Goodno, *National Bioscience Report Shows Industry Robust with Strong Prospects for Growth*, BIOTECHNOLOGY INNOVATION ORG. (June 24, 2014), https://www.bio.org/media/press-release/national-bioscience-report-shows-industry-robust-strong-prospects-growth.

164 *See id*.

165 *Id.*

among scientists for grants and funding from the government and from within the market itself.

Increased competition due to limited resources and the high valuation of blockbuster patents likely means that we will continue to see a growth in the volume of MTAs. Moreover, as more upstream materials and tools are patented, there will be higher amounts of risk, liability, and perceived value when sharing these patented materials and tools. And with academic institutions competing for downstream products and processes, industry partners will similarly be even more cautions when sharing materials because those materials might find their way into back into direct competition with the sharing industry company. This may be in the form of the receiver of a material licensing a product containing the material to a competitor, or the receiver herself may use the material as a foundation to compete in the market.

There is another reason why we will continue to see an increase in MTAs. It is commonly understood that interfirm collaboration is how companies are able to stay abreast of rapid, technology change. Sharing or transferring of materials figures into this interfirm collaboration picture in an important way, since companies do not want to merely borrow or lend materials to other experts in a related or directly analogous field. Companies want to form relationships and ultimately have those experts help them move their particular technology and science forward. In many instances, industry partners are using MTAs as an opportunity to identify and establish working relationships that can lead to further downstream shared innovative activity.

I argue the convergence of academic science, government science, and industry science, along with the more sophisticated fields requiring interfirm collaboration to move forward, are why we are already starting to see a new responsive trend in industry MTAs. As the next Part will illustrate, the direction of MTAs in industry practice is not so much toward new terms, but how lawyers use the MTA. It is not used to set expectations for a one-time interaction like the traditional MTA, but, rather to set up and control repeated interactions like we expect to see in CRADAs or licensing agreements. Accordingly, the function, although not necessarily the form, of many industry MTAs is significantly different than the traditional MTA used in many non-profits and in the majority of academic institutions.

B. A Modern MTA

Industry MTA specialists are taking into account more factors than ever before when setting the parameters of allowed behavior for a recipient of transferred material. These factors are causing tension, however, when industry negotiates with academia. As one industry MTA specialist remarked to me, academics “just don’t get” the factors that go into negotiating and ultimately drafting a MTA. This lack of synergy is even apparent in the literature on how industry scientists describe the value and use of MTAs compared to academic scientists. MTAs are used for more than the physical transfer materials, tools, or data to another party, but also to allow con-

trolled access to materials, tools, or data to help scientists gather information on whether or not they want to work together.

Take, for example, John LaMattina, a 30-year chemist at Pfizer and current director of Zafgen Inc. and Ligand Pharmaceuticals, Inc. When describing a particular project at Pfizer, LaMattina explains that MTAs must "be in place before collaborations occur in order to protect the rights of all involved."[166] He makes this statement when detailing a project that started with a conversation at a conference between a scientist in Pfizer's immune suppression group and a researcher at the NIH.

After this initial conversation, LaMattina states that "the first thing" Pfizer needed was "access" to the particular enzyme that the researcher at the NIH was studying in his lab.[167] Pfizer needed access to evaluate the potential synergy between the researcher at NIH and at Pfizer. This is why the parties quickly drafted and executed a MTA. The MTA carved the pathway to shared innovative activity. Shortly after Pfizer received access to biological materials necessary to further their understanding of the NIH enzyme, the parties confirmed they wanted not just to share materials but also knowledge and personnel.

Because the NIH is a federal agency, the next step in this collaboration was a CRADA. As explained above, the CRADA is a detailed, collaborative agreement between a federal agency and another nongovernmental party(s) under which each makes an intellectual contribution to a joint project. In any given CRADA, there are several layers of contracting, often quite creative and innovative with some enforceable terms and unenforceable terms, to set the expectations and endgame if something goes wrong with the research or the parties during the collaboration.

Examples of enforceable terms are clauses containing third-party infringement warranties and indemnification in the case of a third-party infringement lawsuit. Examples of legally unenforceable terms are those allowing but not requiring the other party to purchase a product (there is no promise made obliging oneself) or those that suggest the parties will use best efforts to produce "something" but how and what they produce is left open for future planning (there is not yet anything to buy or sell).[168] Although those particular terms in modern MTAs are unenforceable in a court of law, they explain and memorialize to the respective parties that there is a shared goal for more interaction. In other words, the modern MTA sets the expectation that these parties are sharing materials in the hopes that it will prove advantageous given each respective party's expertise and know-how to work together.[169]

---

166 LAMATTINA, *supra* note 31, at 44.

167 *Id.*

168 *See* Ronald J. Gilson et al, *Contracting for Innovation: Vertical Disintegration and Interfirm Collaboration*, 109 COLUM. L. REV. 431, 460, 465 (2009) (explaining similar unenforceable terms in John Deere supply and collaboration agreements and an Apple-SCI supply and collaboration agreement) (hereinafter *Contracting for Innovation*).

169 The modern MTA then contains both enforceable and unenforceable terms, creating a "braided"

The MTA between Pfizer and NIH opened the door to the CRADA. A researcher and scientist conversed about their respective projects, realized there was a potential link, and signed an agreement giving access to proprietary (and in some cases patented) materials with the expectation of learning more about each other. The MTA between Pfizer and the NIH facilitated shared innovative activity in this interaction.

A similar interaction involving industry and a federal agency is demonstrated in a 2012 CRADA between Newlink Genetics Corporation and the National Cancer Institute ("NCI") (an Institute of the NIH).[170] The CRADA between these two parties covers the clinical development program of 1-methyl-D-tryptophan ("1MT") to see its effect on various cancerous tumors. But like with Pfizer and the NIH, the CRADA was not the starting point of this collaboration.

In 2007, NewLink and NCI executed a CRADA Letter of Intent to permit preclinical and clinical development of 1MT. In this Letter of Intent, the parties outlined their potential project and its scope. But before the Letter of Intent could be put together, the parties had to learn enough information from one another to evaluate the potential of this project. This initial learning and sharing process that sets the stage is accomplished by a MTA. MTAs also continue to provide access to "Investigational Agent[s]" from NCI to NCI Extramural Investigators" to support the CRADA.[171]

NewLink disclosed a "typical" MTA in its 10-Q disclosure in Appendix C of its NCI-NewLink agreements. So although NewLink did not disclose the particular MTA in this situation, we can still see how NewLink's MTAs differ from the traditional MTA. The NewLink MTA has two clauses that help place the "Research Material" within the bigger "Research Project."[172] This allows NewLink to very clearly define and consequently limit the use of the Research Material. But NewLink also recognizes that there are aspects of the Research Project that are not yet defined, which means that the use of Research Material within that bigger whole might still provide NewLink and the receiver of the Research Material with something unexpected.

In the case where the Research Material leads to something bigger, perhaps a patent disclosure that "claim[s] the use and/or the composition" of the Research

---

contract. *See* Ronald J. Gilson et al, *Braiding: The Interaction of Formal and Informal Contracting in Theory, Practice, and Doctrine*, 110 COLUM. L. REV. 1377 (2010) (hereinafter *Braiding*). This "contracting for innovation" will be discussed in the next section. *See Contracting for Innovation*, *supra* note 168 at 431, 432 (term used by Gilson, Sabel, and Scott to describe unique contracting practices used by parties to help develop relationships and trust in field of science and technology).

170 On file with author.

171 *Cooperative Research and Development Agreement for Extramural-PHS Clinical Research*, SEC. AND EXCH. COMM'N, http://www.sec.gov/Archives/edgar/data/1126234/000112623412000024/nlnk-20120331xex106.htm (last visited Jan. 27, 2015).

172 *Id*. at 97.

Material, NewLink uses normative terms to set the parties' expectations. For example, the parties will enter into a licensing agreement "on terms to be negotiated in good faith by the Collaborator[s] and Institution," the "Institution agrees not to offer to license [the Invention] on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator," and "Institution agrees to file and prosecute patent application(s) diligently and in a timely manner." All of this is premised on an action that the parties do not have to take if they do not want to; and, hence we see an unenforceable clause within a broader (and enforceable) contractual agreement.

When both parties are from industry, there is more fluidity in the agreements and stages of shared innovative activity. In the Sangamo Biosciences, Inc. ("Sangamo") and Sigma-Aldrich Co. LLC ("Sigma") License Agreement, as of September 2, 2014, there are six amendments to the original agreement dating back to July 10, 2007.[173] In 2007, Sigma gained access, or as the parties stated, "a certain license to use Sangamo's proprietary zinc finger protein [ZFP] technology." The sixth amendment is meant to "provide Sigma with greater flexibility."[174] Like with several of the terms above, it is not clear how to measure or enforce this particular term.

Nevertheless, it memorializes the flexibility and fluidity of the licensing agreement based on Sigma's access to Sangamo's ZFP technology. It also demonstrates that the parties have mutually agreed to amend the legally governing contracts when needed instead of attempting to figure everything out in one contract upfront—and before the parties have any real idea of the scope of likely success of the collaboration. With the first agreement, providing mutual access to one another's materials, research tools, and/or data, a relationship is formed. Down the line, and with forward-looking and normative terms, this relationship has evolved into sharing know-how, decision-making, and profits.

Another Sangamo license agreement, this time with an international industry partner, Shire AG, again models the modern MTA. This particular agreement is termed a "collaboration and license agreement" and provides Shire AG access to Sangamo's ZFP technology similar to the access it gave to Sigma back in 2007, but it is more than a transfer or access to materials and data related to Sangamo's ZFP technology.

In this particular agreement between Sangamo and the Swiss company, the parties are using the license agreement to set the broad expectations for future shared innovative activity. In the parties' words, their "desire [is] to engage in a collaborative research program to identify products and processes employing Sangamo's zinc finger DNA-binding technology for treating certain diseases caused by particular

---

[173] *See* License Agreement between Sangamo Biosciences, Inc. and Sigma-Aldrich Co. (on file with author).

[174] Attached to this agreement is another amended license agreement between Sigma and a buyer that is simply correcting one definitional term in an earlier agreement whereby Sigma sold cell lines that it created under the original license agreement with Sangamo.

monogenic defects, which can be advanced into human clinical trials and following regulatory approval, commercialized."[175] Shire is given complete discretion to commercialize any Shire ZF Product it develops in this agreement, and it will do so using "Commercially Reasonable Efforts."[176]

Just like with a traditional MTA, there are the commonplace disclaimers of any warranties and with the ownership of the original technology staying with the supplier (in this case Sangamo), but there is also use of language like "reasonably," "good faith," and "diligent."[177] There is the floor of the agreement—Sangamo owns everything and claims no knowledge of infringement and no acceptance of any responsibility of what Shire does—and there is the ceiling of the agreement—where Shire is allowed to basically do anything it wants (within the law of course) with technology it develops in this collaborative relationship. There is also a licensing fee floor, in this case, $13 million, with a flexible ceiling based on percentages of products sold. In-between the floor and the ceiling the parties will work together guided by a joint steering committee ("JSC") that can solve problems as they arise.

One last example of a modern MTA is the "Co-Development and Collaborative Agreement" between two between Aveo Pharmaceuticals, Inc. ("Aveo") and Biodesix, Inc. ("Biodesix").[178] On August 17, 2009, the parties entered into a "Mutual Confidentiality Agreement," likely where the parties got together to discuss possible collaboration.[179] The next (at least publicly available) agreement is a MTA that was effective starting April 5, 2011, and that was amended three times after 2011 (April 1, 2013, May 21, 2013, and April 4, 2014).[180]

Aveo agreed to supply to Biodesik with Ficlatuzumab, a "potent hepatocyte growth factor (HGF) inhibitory antibody that binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities."[181] In addition, Aveo agreed to supply to Biodesik clinical specimens (including "samples, tissues, fluid, and other biological and pharmaceutical materials generated or obtained in connection with this Agreement or the MTA") so that Biodesik could further develop and commercialize Ficlatuzumab.[182] Like with Sangamo and Sigma, Aveo and Biodesik continued to amend the MTA to reflect the growing and changing interfirm collaboration.

Overall, the modern MTA is not static. It is dynamic and opens the door for shared innovative activity. It does not matter whether it is the NIH or a subsidiary of

---

[175] *Supra* note 173.
[176] *Id.*
[177] *See id*.
[178] *See* Co-Development and Collaboration Agreement between Aveo Pharmaceuticals, Inc. and Biodesix, Inc. (on file with author).
[179] *Id*.
[180] *Id*.
[181] *Our Product Candidates*, *Ficlatuzumab*, AVEO ONCOLOGY, http://www.aveooncology.com/our-product-candidates/ficlatuzumab/ (last visited Jan. 27, 2015).
[182] *See supra* note 178.

it like the NIC, an international not-profit cooperation,[183] an American non-profit foundation,[184] or another industry partner,[185] and it does not matter what the parties call the particular agreement(s); tracing the steps leading to the in-depth research collaboration is substantially similar. And most importantly, here, the MTA or "License Agreement" that gives access to materials opens the door after an initial conversation in which scientists learn that they want to explore opportunities of shared innovative activity that can more efficiently move a field forward than working on their own. The drafter of MTAs must understand what kind of collaboration is desired: a one-time interaction between the parties where a quick transfer of material is to take place and nothing more, or a transfer where the aim is to gain access to a material or tool in order to evaluate whether more in-depth collaboration between the parties is desirable.

Given this information, it makes sense that industry partners are not taking time to respond to many requests for materials from academic institutions. It is billed as just that—a one-time, arm's-length interaction with little lead-in conversation. Industry partners would rather respond to a request where there is more interest and attention to getting to know one another.

Of course, not every interaction must or necessarily should be one that will result in repeated interactions. That said, I do assume here that society should want to encourage this type of interaction, as both noncommercial and commercial scientists at academic institutions, research laboratories, and companies realize that in order to stay competitive and to make a difference in a highly sophisticated and fast-moving technological world, collaboration among specialists is needed. The following section addresses how to bridge the gap between the traditional MTA used heavily by academic institutions and the modern MTA used heavily by pharmaceutical and biotech companies. There is a time and place for both, but identification and communication of research goals must be communicated between scientists and then between lawyers in order to avoid long delays or simple failures to negotiate and execute a license.

III. Bridging the Gap and Moving Forward

The difference between the traditional and modern view of MTAs is perhaps most recognizable in how scientists based in industry, academia and even government frame their use of, and complaints about, the material transfer process. LaMattina remarks that the first formal step in possible collaboration between Pfizer and HIH researchers was to get access to NIH's of-interest enzyme, and that a MTA

---

[183] *See, e.g.*, Collaborative Research and Development Agreement between the Swiss not-for-profit and 4-Antibody AG, a private pharmaceutical company based in Europe that was recently acquired by Agenus Inc., a Lexington, Massachusetts-based biotechnology company (on file with author).

[184] *See, e.g.*, Research Agreement between Anacor Pharmaceuticals, a biopharmaceutical company based out of Palo Alto, California and the Bill and Melinda Gates Foundation, a Washington charitable trust and tax-exempt private foundation (on file with author).

[185] *See, e.g.*, *supra* note 178.

gave this access while also protecting "the rights of all involved."[186] In reference to how industry and academia interact and negotiate MTAs, lawyers and MTA specialists at biotech firms seemed frustrated with their interactions with academic institutions. They voiced complaints that the academic institution did not understand the big picture.

Academics seem to share a similar sentiment about industry scientists and lawyers. When talking to and reading the work of academia transfer specialists, they have consistent complaints about academia-industry MTAs. The most voiced and documented complaint is the amount of time it takes to negotiate MTAs with industry partners, especially when compared to the time it takes to negotiate and execute MTAs with fellow academic institutions. Academic institutions want a quick interaction that allows them to continue working on their own with their specific research projects and grants.

But why in particular does it take more time to negotiate a MTA when the other party is an industry partner as opposed to another institution? This gets to the second consistent complaint of academic transfer specialists: industry asks for too much in MTAs. Industry wants to begin a collaborative relationship with a MTA, and largely, academic institutions do not.

This divergence is seen in a report prepared by the Office of Research and Development at the U.S. Environmental Protection Agency in response to President Obama's 2011 Memorandum on "Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Business ("EPA Report")." The EPA Report sheds light on how government agencies view "collaborative partnerships." Although in many ways government agencies are unique in their research and each agency works a bit differently, I found in my research that academic institutions are quite similar to government agencies such as the NIH in contracting practices and views of MTAs.

Remember that a CRADA "is the main vehicle" for partnerships with the government that aims at the creation of commercial activity and growth of the economy.[187] This is in contrast to a "Materials CRADA." The EPA Report states that a Materials CRADA "is used when there is a minimal amount of collaborative research and an exchange of research materials." And, lastly, "[w]hen an exchange of research materials is desired with no collaboration, [this] is when a Materials Transfer Agreement (MTA) is used."[188]

This chestnut gets to the heart of the disconnect between the traditional MTA and the modern MTA: the function of the traditional MTA is to simply exchange

---

[186] *See* LAMATTINA, *supra* note 31, at 44.

[187] Presidential Memorandum – Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Business, U.S. ENV'T. PROT. AGENCY (Oct. 28, 2011), *available at* http://www.nist.gov/tpo/publications/upload/EPA-Tech-Transfer-Plan.pdf.

[188] *Id.*

materials with no collaboration while the function of the modern MTA is to open the door to future collaboration. Now that the different functions of the MTA are known, lawyers have an opportunity to bridge the gap for their respective clients and ensure that legal process is not holding up scientific innovation. Instead, legal process should actively help foster more opportunities for shared innovative activity.

Lawyers must quickly determine what type of MTA is most desirable. Furthermore, they must be able to get past particular problematic terms in industry-to-academic transfers. There are three such terms that academic institutions complain of most frequently when contracting with an industry partner. Each of these three terms will be discussed below with suggestions for how to overcome this current gap between the traditional MTA and modern MTA. This discussion offers simple but effective ways that the traditional MTA can be updated so that when a one-time interaction is desired by a requesting party, the party can clearly communicate this expectation while also giving the other party the protection and potential options it feels it needs in order to not only make it worth its time, but also advantageous to effectuate the transfer.

A. One-time Interactions: Contracting Around Contested Terms

The first term causing delays in transfers is indemnification, the second is ownership, and the third discussed here is publication. There are some transfer specialists that point to the simple, but important fact that academic institutions implicitly understand the constraints and goals of other academic institutions. This is why in part the academic-to-academic transfers appear to be easier than industry-to-academic transfers. There is a commonality of core missions. Many academic institutions and faculty members share the fundamental understanding that their research is first and foremost noncommercial in nature, as well as that there are limitations to what the administration at their respective institutions will and will not support.[189]

Yet there are concerns that as grants become more competitive among principal investigators, anti-collaborative behavior will be encouraged. Conversations with scientists and scholars indicate that this is a legitimate concern, and, further, that it may already be taking place. All the more reason that the MTA literature must continue to progress in academia so that there will be better lawyering that furthers the mission to foster shared innovative activity for the greater public good.

Focusing here on academic-to-industry transfers, there are several reasons that these transfers are "much more complex" and "much more prone to failure."[190] As detailed above, the core mission of academic institutions is generally to support the pursuit of knowledge and dissemination of such knowledge to the public. This may

[189] *See* Bennett et al., *supra* note 86, at 703 (stating that the "[s]haring of materials between university scientists is generally less problematic than transfers between industry and academia, primarily because the cultures and motivations of each institution involved in the exchange are similar").

[190] *See id*.

be contrasted with an industry partner's goal of maximizing its profit, which is achieved by quickly bringing a product or process to the market. The starting points are not the same, causing misunderstandings in upstream negotiations. Beyond the contrasting missions of academic and industry parties, another reason is because the industry partner often wants too much from an academic institution, or at least too much from an academic institution's perspective.[191]

This is particularly hard to understand for industry parties as some academic institutions are aggressively licensing their technology and in some cases acting like a so-called patent troll.[192] As a consequence of this recent shift in academic institutions towards protecting and enforcing intellectual property rights, industry partners may view academic institutions as competition. Instead of playing a supporting role as noncommercial scientists focused in basic science that generate developments that will in turn be passed to industry partners through publication, presentation, or explicit long-term partnerships, academic science has evolved such that academic institutions are a key player in markets. Faculty are encouraged to disclose their ideas and discoveries to their respective technology transfer office so that the technology transfer office can help protect and develop these ideas into a marketable downstream product or process. On one hand this evolution may help decease the gap in missions between academic institutions and industry players, creating more synergy between the two and making research and development agreements easier to come by, yet it is also confusing to industry parties. Overall, however, academic institutions remain largely different than their industry counterparts. This is because the core mission and structure of the university remains the same despite the interest in capturing the downstream market.

The first contested term discussed here—liability and/or indemnification—reflects this difference. Parties, and not just those involved in technology transfer negotiations, do not like to accept liability for others' actions or the duty to indemnify another party. In academic science it is common for the recipient of the material, as evidenced by the UBMTA, to take responsibility for "its use, storage or disposal of the Material."[193]

---

[191] *See Redeploying Bayh-Dole*, *infra* note 196, at 914 (explaining that "[o]verly aggressive industry demands regarding access to research results, failure to properly address conflicts of interest, and unnecessarily strict prohibitions on timeliness of publication or sharing of information can all interfere with proper academic priorities").

[192] *See* Lemley, *supra* note 29; *see also* Nick DeSantis, *Judge Adds $366-Million to Patent-Lawsuit Award for Mellon*, THE CHRONICLE OF HIGHER EDUC. (Apr. 1, 2014), *http://chronicle.com/blogs/ticker/jp/judge-adds-366-million-to-patent-lawsuit-award-for-carnegie-mellon-u* (discussing reward amount for Carnegie Mellon in a patent infringement suit where Carnegie Mellon did not make, nor use, the infringed technology). Recent university practices also show that "there is little indication that universities are particularly effective or enlightened stewards of technology." Lee, *supra* note 29, at 80 (further explaining that "in cases involving human embryonic stem cells, cotransformation, and genes related to breast cancer, universities have exhibited many of the same rent-seeking, self-interested tendencies as commercial entities.").

[193] *See* UBMTA, *supra* note 44.

Standardized university-specific forms also include an indemnification clause. For example, the UC-Irvine MTA states that the "Recipient Institution will defend, indemnify and hold harmless The Regents for all claims, losses and expenses resulting from your use of the Biological Materials."[194] From these traditional MTAs, one learns that transferors want the recipient of the material to take responsibility for their own actions and use of the transferred material, as well as to take on the risk that if anything goes wrong (for example, the use of the material infringes upon another's patent or a laboratory accident occurs), the recipient will defend and hold the transferor harmless. However these standardized intake MTA forms are misleading in some cases. Although it is common to include a liability clause, an indemnification is often a deal-breaker for academic institutions. This is so even though academic institutions include the clause in their own MTAs.[195]

The indemnification clause is problematic for academic institutions for two reasons. First, there are many states that prohibit their state institutions from indemnifying other parties. This includes states such as Alabama, Georgia, Kentucky, and New York.[196] Second, even when state law does not expressly prohibit taking on the risk to indemnify another party, the academic institutions' own internal policies prohibit the practice. Academic institutions are risk averse.[197] Academic institutions will not take on the risk of a patent infringement claim, and as we have seen repeatedly in the last decade, such claims can easily cost millions of dollars to defend.

However, technology transfer offices must understand a particular reason that industry partners fight so hard to shift risk to academic institutions when transferring materials, tools, or data. If the industry partner is working with a public institution, then that public institution, as an arm of the government, may claim the protection of sovereign immunity.[198] This means that if the public institution infringes another's rights, and assuming the government or institution did not expressly accept risk in some way, sovereign immunity may mean that the aggrieved party must seek other avenues to recoup some of the lost value of its patented or otherwise protected technology.[199] In short, the aggrieved party will look to the licensors or con-

---

194 Univ. Cal. Irvine, *supra* note 124.

195 The practice of universities demanding that others indemnify them sometimes goes even further. John Tyler of the Kaufmann Foundation explains that "[a]n extreme, but not unheard of . . . behavior is for a university to demand that its licensee indemnify the university if the research results it is licensing infringe or if the university actually lacks the right to license it." This type of aggressive licensing is overreaching behavior on the university's behalf that "inhibits commercialization and utilization and undermines the [Bayh-Dole] Act's purposes." John E. Tyler III, *Redeploying Bayh-Dole: Beyond Merely Doing Good to Optimize the Potential in Results of Taxpayer-Funded Research*, 38 J. TECHNOL. TRANSF. 911, 925 (2013) (hereinafter "*Redeploying Bayh-Dole*").

196 *See* Bennett et al., *supra* note 86, at 702.

197 *See id*. at 704 (explaining that universities are most concerned in transfer agreements with "the fundamental mission of the institution and their low tolerance for financial or legal risk").

198 *Redeploying Bayh-Dole*, *supra* note 196, at 926.

199 *See id.* (explaining that a consequence of a university claiming the protections of sovereign immunity "could force a victim of university infringement to pursue the best available alternative—the party to whom the university licensed its innovation.").

tributors to the university's infringing technology, especially the university's industry partners that may have deep pockets.

When transferring technology and sharing materials, tools, and data, academic institutions have the opportunity to use innovative contracting to manage expectations and set up a mechanism to help maintain these expectations in the face of uncertainty and risk. If industry partners are demanding the academic institution to indemnify and defend it in the case of a third party suit, and the academic institution will not do so, the parties may achieve a compromise using warranty and representation clauses.

The academic institution can take on some risk by making reasonably informed decisions about how the material will be used and what type of due diligence has been performed about the research project that the material or tool will be used to support. By representing to the industry partner that the principal investigator has worked with the technology transfer office (and most likely a registered patent attorney), and that to the best of its knowledge the university's use of the transferred material will not infringe a third party's rights, an industry partner may be satisfied despite the lack of a traditional indemnity clause.

The university can also contractually warrant to keep the industry partner apprised of any potential third party violations, even if it appears, at least at first, to involve the entire project (as opposed to the use of the tool). This will help industry partners know that an academic institution understands the risk involved and that it will take measures to keep the industry party apprised of any potential problems with the shared material. This very simple yet potentially effective workaround to the traditional indemnification clause can refocus the conversation when academic institutions and industry parties stalemate during an indemnification negotiation, allowing them to move past the oft-contested term and spread the risk and uncertainty of infringement and lab accidents.

The second term that causes delays is the ownership of resulting innovations, and really the royalty possibilities, if the academic institution brings a product to market or sells the product to another. The rights to any intellectual property developed in part or whole from transferred material is arguably the hardest to negotiate. The reason is money, or at least the opportunity for money. And if money is not possible, a second best option is access to any developed know-how or technology created using the shared material. Both parties, whether industry or academic, understand the value of cash flow in research and development is often just as important as avoiding existing patents while conducting research and development. Money and access to technology can lead to better innovation, and, again, more opportunities for royalties from downstream research and development.

Wanting to make money after letting another scientist borrow something valuable is not a bad objective. After all, it likely cost the transferring party time and money to create the material that was transferred. That said, royalty and access

clauses might quickly become non-collaborative terms of a MTA when the transferring party overreaches.

One often overlooked impact of fundamental differences in mission and structure of academic institutions compared to industry parties is that academic institutions may not be able to give ownership rights or access to fruits of research in a way that industry most desires and is accustomed to receiving when dealing with another industry party. This is not because of restrictions that the academic institution put on itself, but rather governmental restraints.

Most notably, academic institutions are often private and public non-profit universities that have obtained tax-exempt status under Internal Revenue Code ("IRC") section 501(c)(3).[200] In addition, some universities have received U.S. federal tax-free status on bonds issued to build or improve research facilities.[201] This tax-free status means that the vast majority of universities and teaching hospitals are subject to particular regulations of activities. The relevant IRC rules that attach to the tax-exempt status and legally restrain university activity deal with the licensing of inventions and the acceptance of money for sponsored research.[202] This does not mean that universities will lose their tax-exempt status if they license their inventions or receive money for sponsored research activities, assuming that they are indeed set up and in fact operating for "educational" purposes to "carr[y] on scientific research in the public interest."[203]

Academic institutions subject to these regulations bear the burden to prove that their primary purpose is "scientific research in the public interest," and although the regulations do not precisely define what is or is not "scientific" there is a helpful court construction of the term.[204] The Court of Claims, precursor to the Federal Cir-

---

[200] *See Redeploying Bayh-Dole*, *supra* note 196, at 914 (explaining that "industry often fails to appreciate that U.S. universities must comply with a regimen of laws and regulations relating to their status as either governmental bodies or public charities under section 501(c)(3) of the Internal Revenue Code"). *See also supra* note 197, at 701-02; Sean O'Connor et al, *Legal Context of University Intellectual Property and Technology Transfer*, prepared for *The Committee on Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue*, National Research Council, The National Academies, September 20, 2010, at 74 (hereinafter *Legal Context of University IP and Tech Transfer*). Even though these academic institutions may not pay federal taxes, they may pay unrelated business income taxes (UBI). *Id*.

[201] *See supra* note 197, at 701.

[202] *Legal Context of University IP and Tech Transfer*, *supra* note 200, at 74. For a thorough treatment of tax-exempt universities, see Peter D. Blumberg, *From "Publish or Perish" to "Profit or Perish: Revenues from Technology Transfer and the 501(c)(3) Tax Exemption*, 145 U. PA. L. REV. 89, 115 (1996).

[203] IRS Reg. 1.501(c)(3)-1(d)(5)(v) (2014), 26 C.F.R. 1.501(c)(3)-1(d)(5)(v)("The fact that any organization (including a college, university, or hospital) carries on research which is not in furtherance of an exempt purpose described in section 501(c)(3) will not preclude such organization from meeting the requirements of section 501(c)(3) so long as the organization meets the organizational test and is not operated for the primary purpose of carrying on such research.").

[204] *Legal Context of University IP and Tech Transfer*, *supra* note 200, at 75-76.

cuit, defined "scientific" research quite broadly.[205] If the research meets one of the following criteria, then it is likely deemed "scientific" for purposes of the IRS regulations:

> (1) involved the use of observation or experimentation to formulate or verify facts or natural laws; (2) could only have been performed by an individual with advanced scientific or technical expertise; (3) added to knowledge within a particular scientific field; (4) involved the application of mathematical reasoning; or (5) was an attempt to systematize or classify a body of scientific knowledge by collecting information and presenting it in a useful form.[206]

Academic institutions then have a relatively easy time retaining their tax-exempt status when they conduct research. The research is carried out by faculty members and graduate students who have a high degree of scientific expertise, and the research is done to either aid students in learning, is ultimately published, and often is linked to the community with hopes to positively impact the economic climate or surrounding industry. This said, the IRS is aware of recent changes in academic science. In 2008, the IRS sent approximately 400 compliance questionnaires to colleges and universities that focused on, among other things, how academic institutions reported revenues and expenses from their activities that generated unrelated business income during the tax year ending in 2006.[207]

An academic institution may lose its tax-exempt status if it is not careful when managing its intellectual property portfolio. This impacts the way that academic institutions interact with industry partners, which industry partners often do not fully understand because they are not subject to these specific IRS Regulations. This is an area that good lawyering can help improve. A 501(c)(3) scientific organization will not keep its status "if an organization (1) retains (directly or indirectly) the ownership or control of more than an insubstantial portion of the patents, copyrights, processes, or formulae resulting from its research *and* (2) does not make such intellectual property available to the public."[208]

The IRS Regulations are clear that granting exclusive licenses is disfavored and such licenses are only to be given when an exclusive license is "the only practicable manner" that allows for the intellectual property or know-how to benefit the public.[209] Otherwise, the intellectual property or know-how should be made available to the public on a nondiscriminatory basis, presumably in the form of nonexclusive li-

---

[205] IIT Research Inst. v. United States, 9 Cl. Ct. 13 (1985).

[206] *Legal Context of University IP and Tech Transfer*, *supra* note 201, at 75-76. The Court of Claims' construction of what is scientific research for purposes of IRC rules is buttressed by the IRS regulations. These regulations provide a bit of guidance in regards to what does not constitute scientific research: for example, "the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc." IRS Reg. 1.501(c)(3)-1(d)(5)(ii), 26 C.F.R. 1.501(c)(3)-1(d)(5)(ii).

[207] *See Statement on the IRS Compliance Questionnaire for Colleges and Universities*, AGB/NACUBO (Dec. 17, 2009), *available at* http://www.nacubo.org/Documents/BusinessPolicyAreas/AGB_NACUBO_IRS_Compliance.pdf.

[208] 26 C.F.R. 1.501(c)(3)-1(d)(5)(iv).

[209] *See* IRS Reg. 1.501(c)(3)-1(d)(5)(iv)(b), 26 C.F.R. 1.501(c)(3)-1(d)(5)(iv)(b).

censes or by placing it in the public domain. Accordingly, when industry partners and academic institutions are negotiating the transfer of materials, research tools, or data, academic institutions have restrictions on what they can and cannot offer to incentivize the industry partner to make the transfer. Exclusive licensing opportunities are rare for industry partners and they need to understand that a refusal by an academic institution to grant one is not based just on economical considerations but also on compliance with federal law. Demanding an exclusive license to use any resulting intellectual property from the use of the industry material, tool, or data is a deal breaker for academic institutions.

This is further buttressed by NIH Guidelines that counsel parties not to exclusively license research tools, reflecting a concern that access to tools is a key component to innovation. Only if an exclusive license cannot be avoided does NIH find that an exclusive license may be an acceptable if "the licensor retains rights to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available." [210] Other options should be explored before walking away from the negotiation table but again, industry counsel must understand that academic institutions are not as free to easily consider some of the more common ownership licensing options. Most notably, three that are often in play during MTA negotiations are reach-through royalties, grantbacks or a first right of refusal option, and field-of-use restrictions. Each comes with its own set of complications.

Reach-through royalties are controversial at best, and at worse, run afoul of the patent misuse doctrine and antitrust laws. A reach-through royalty is when parties agree that one has the right to "reach through" the unknown nature of future technology and capture the right to royalties of a successful commercialization of the previously unknown technology.[211] Take a research tool, for example, that an industry partner shares with an academic institution. Suppose the industry partner completes the transfer with no transfer fee because it was too hard to determine the value of the research tool to the academic institution (or, also as likely, the academic institution does not have sufficient funding for acquiring the use of research tools). Instead, the transferring industry partner obtains the right to capture some portion of any valuable intellectual property the academic institution creates with the use of the transferred research tool. This is a classic use of a reach-through clause in a MTA. It allows the transferring party to claim some of the profits of the later developed invention or new process.

For research tools in particular, commentators have voiced concerns that reach-through royalties stifle downstream innovation[212] and may contribute to a growing

---

[210] *Supra* note 101, at 72095.

[211] *See* Alfred C. Server et al, *Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools*, 1 HASTINGS SCI. & TECH. L.J. 21, 22 (2009).

[212] *See id*. at 23 (explaining that "tool users, among others, argue that the excessive protection of research methods and tools, particular reach-through protections, stifles downstream drug development efforts to the detriment to the public").

anticommons.[213] Moreover, some commentators have voiced concern that reach-through royalties are contributing to the decline in the sharing ethos.[214] Yet proponents of reach-through royalties argue that they allow for more creative ways to ensure that the right incentives are in place to encourage and facilitate research and development (most notably in expensive innovation industries such as pharmaceuticals).[215] They also point to small biotechnology companies that market their research tools which arguably helps others in their research and development.[216] For these small firms, the licensing of these research tools is their main source of income.[217]

Reach-through royalties were such a concern, especially with the transfer of research tools and the drama of the Harvard oncomouse, that the NIH specifically prohibited this licensing practice in its 1999 guidelines. The NIH Guidelines responded to a commentator that advocated for the use of reach-through rights for those recipients who cannot afford to buy or license tools to nevertheless still obtain access in return for giving up some percentage of profits from a possible later developed product or process.[218] The NIH responded that despite this seemingly persuasive reasoning, the NIH "finds that such practices contribute not only to specific restriction of access to subsequent tools arising out of the NIH-funded work, but also to the general proliferation of multiple ties and competing interests that is the source of the current access problems."[219] In even stronger language, the NIH stated that it "does not support the coupling of procurement with intellectual property rights and restrictions and expects Recipients to ensure that NIH-funded tools are not restricted as a result of such agreements."[220]

The NIH Guidelines are applicable to those that receive NIH funding, including non-profits, universities, and private companies.[221] One particular reason why reach-through royalties are still an issue more than ten years since the guidelines were published is because it is large companies that often have the research tools that academic institutions want to use. Those large companies are not often recipients of NIH funding, unlike several of their much smaller competitors. These companies have the money and tools and can name their terms. Technology transfer

---

213 *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998).

214 *See* Kimberlee A. Stafford, *Reach-Through Royalties in Biomedical Research Tool Patent Licensing: Implications of NIH Guidelines on Small Biotechnology Firms*, 9 LEWIS & CLARK L. REV. 699, 700 (2005). *See also* Strandburg, *supra* note 39, at 2259 (explaining that "[b]esides sometimes failing to receive materials requested from industry suppliers, academic scientists complained of requests for onerous terms of transfer, such as reach-through royalties").

215 *See id*.

216 *See id*.

217 *See id.*

218 *See supra* note 101, at 72091.

219 *Id.*

220 *Id*.

221 *Id*.

specialists have reported that in their experience, transfers from industry to academic institutions (even as large as the UC) are often low priority.[222]

So if industry is less likely than ever to share materials, tools, and data with academic institutions because they view academic institutions as competitors, albeit competitors who cannot afford to pay for the materials upfront, what can be done to help move the transfer process along? Academic institutions have to give industry partners a reason to let them use their materials or tools. Most academic institutions cannot pay for the use of these tools upfront, hence the need, at least in part, for reach-through royalties partners.

Although reach-through royalties do have a negative reputation and a lot of fear surrounds them because of downstream access to technology, innovative contracting offers the ability to creatively contract around the problematic aspect of reach-through royalties. Instead of completely banning reach-through royalties, like the NIH recommends, academic institutions should embrace the negotiation power the possibility of reach-through royalties gives them. Certainly academic institutions must do so with caution to ensure that a reach-through royalty clause does not restrict further research. If an industry partner demands not only future royalties of any resulting technology created with the transferred tool, but also some sort of power over how the tool or created technology is used, this can stifle downstream opportunities with third parties. This is when academic institutions and industry transfers will fail.[223]

One way for academic institutions to successfully use reach-through royalties as a bargaining tool, one that will not impact the way that academic institutions bring their products or processes to market, is to allow some form of reach-through on value but not use of the technology. In this manner, reach-through royalties should be limited to royalties on future technology. This should likely be a flat or tiered percentage of the sales with an aim towards capping the total royalties at an amount the parties agree to upfront. This allows industry to regain the value of their shared material or tool that the academic institution could not or would not pay upfront, while allowing unfettered sharing and/or transferring of the altered material or tool.

Another way industry can partner with academia successfully when transferring materials, tools, or data is by acquiring a "grantback" right to use the invention that comes out of the academic institution using the transferred material. And if not a grantback, then perhaps an "option" to be the first party to negotiate for the right to license the technology would work effectively. It is in the industry party's best interest to ensure that it gets a grantback right to use any of the created technology, or at least the first option to negotiate a license to use the technology. This enables the industry party the chance to recoup any money it spent to create the materials or

---

[222] *See supra* note 14, at 2.

[223] *See id* (citing "the need to avoid creating conflicting legal obligations with third parties" as a top concern of universities when negotiating technology transfer with industry partners).

tool that was transferred, as well as bring the academic institution's new invention to the public. Technology transfer offices find this much less controversial than reach-through royalties, and "in many cases" they find themselves in a better position to make this sort of concession.[224]

One note of caution here is that a grantback or option to be the first negotiator is only an attractive substitute for reach-through royalties if the original grantback is not an exclusive right to use. In essence, the industry transferor is negotiating for the right to use the technology in its practices but not for the power to prevent others from also using the academic institution's technology, including the academic institution itself. If the academic institution is going to take on a responsibility for no upfront consideration, it needs to make sure it is not hamstringing itself down the road. The goal is to quickly and efficiently get the academic institution's faculty output disseminated to the public, and this is most often done by making the technology widely available to other noncommercial and commercial scientists.

Another way that academic institutions can help encourage industry partners to execute technology transfers is to ensure that the academic institution does not act as a direct competitor and/or help another direct competitor of the industry partner. This may be achieved by using a field-of-use restriction clause. This clause will restrict the academic institution's right to use the material for a particular type of research, mainly noncommercial research. This clause has the potential to further principal investigators' work that is still at the upstream research process, but it is best used cautiously at academic institutions when they are contemplating downstream research and application. This is because a field-of-use restriction may prevent the academic institution from disseminating the resulting invention to the public if it will be doing so for money either by selling the resulting product or process itself or licensing others to do so. In contrast, field-of-use restriction clauses can more liberally be utilized to gain access to materials, tools, or data when the recipient of the material is still conducting upstream research.

Yet there are negatives to field-of-use restrictions and use restrictions more generally. These all hinge on the fact that ownership stays with the provider of the material and, consequently, the provider restricts the recipient's use of the material in its upstream or downstream research. In essence, the provider narrows the ways that the recipient is allowed to use the transferred material. This is especially so when the materials or tools are in the biomedical field.

For example, when WARF collected human embryo donations, the consent forms contained promises to the donors regarding the subsequent use of the embryo cells (for example, "that cells would not be combined 'with a nonhuman embryo,' that could prevent 'important research'").[225] From these donations, and after a Wis-

---

[224] *See supra* note 197, at 702 (discussing that in three technology office specialists' experience, "the recipient, in many cases, may be able to grant a first right or an option to negotiate a non-exclusive or exclusive commercial license to such inventions").

[225] John M. Golden, *WARF's Stem Cell Patents and Tensions Between Public and Private Sector Ap-*

consin-Madison scientist and his team developed long-lasting primate embryonic stem cells, WARF obtained three broad patents on human embryonic stem cells and cell lines (hESCs).[226] WARF then transferred hESCs lines to requesting academic institutions with executed MTAs (and, at least originally, $5,000). A controversial use restriction within the MTAs was that researchers were barred from sharing hESCs "with others" and that researchers had to show annual research plans for use of the hESCs.[227]

To many researchers these use restrictions were contrary to the very purpose of academic science—to promote scientific progress and dissemination of new knowledge and products to the public.[228] But these use restrictions were designed at least in part due to the promises WARF made to the donors. This contract-within-a-contract or "nested contract" problem is common in academic research, demonstrating the need to carefully draft the original consent forms when collecting materials and data. A use restriction such as sharing with others is non-collaborative and should be avoided by limiting early promises to donors and elsewhere. Reassurances of ethical scientific experiments may be necessary but the scope of use of materials is often changed or altered upon advancement in a scientific field. Keeping broad language in original consent forms will help enable adaptability in further use of the collected materials.

Ultimately, with the right combination of pressure through "criticism by academic scientists and representatives of government institutions that provide significant funding of health-related research," in addition to "co-opting activity," "most notably, by the [NIH's] choosing WARF's subsidiary WiCell to be the host of the National Stem Cell Bank," WARF liberalized its use-authorization practices.[229] This also arguably shows that WARF had more ability to contract around its original promises to donors, perhaps by including a more narrow field-of-use restriction instead of a general use restriction.

The final most often contested term in industry-to-academic transfers involves publication rights. Academic scientists are concerned about rights to publish and present results and conclusions of the research conducted with the use of shared materials, tools, or data. This is so not only because of the pressure to "publish or perish" in academia, or necessarily to maintain tax-exempt status, but also because it is the culture in academia to share knowledge with other scientists and the public through publication or presentation. If another academic institution or industry partner attempts to control the dissemination of research results or conclusions through a publication restriction in a MTA, it may lead to a failed negotiation. Although many academic institutions are willing to send the provider of a material a copy of a manuscript or notes of a presentation and give the provider 30 to 60 or so days to

proaches to Research, 38 J.L. MED. & ETHICS 314, 319 (2010).

226 *Id*. at 315.

227 *Id*. at 319.

228 *Id*.

229 *Id*. at 318.

approve it, that is all an academic institution will routinely agree to when negotiating a material transfer.[230]

Publication restrictions also come in the form of attribution to the provider. Both the UBMTA and the NIH SLA require proper attribution be given to the source of any material used.[231] No co-author attribution is warranted unless there is a more in-depth collaboration beyond merely sharing materials. There are some surprising stories of providers demanding co-authorship, but those are few and far between and should promptly be denied as unethical and overreaching. Research shows that while this is of primary concern to academic scientists, it is often easily negotiable once the provider is reassured that it will have a chance to review any paper prior to publication.[232] Like with indemnification and ownership, academic institutions can take calculated risks here by ensuring that the industry's period to review or file a patent is limited and does not extend to control over the actual results of tests or ultimate publication.

B. Fostering Shared Innovative Activity: A Modern MTA

The difficult part about the use of the modern MTA is not about particular terms like with the traditional MTA, although similar stalemates can occur, but rather the high level of uncertainty inherent in embarking on a collaborative journey to create "something." If just one party undertakes the journey, information costs, opportunism, and hold-up risks are decreased. Innovation and the progress of science moves faster, however, when there is a collaborative and iterative process of multiple parties combining their different skills and resources together. This means that parties will need to share highly proprietary and valuable information, as well as personnel and resources, in an environment that is not only uncertain but ripe for opportunism and hold-up.[233]

How can we best support and thereby encourage collaboration while also decreasing opportunities to exploit information and resources or hold up innovation for purposes of personal gain? Recently, Ronald J. Gilson, Charles F. Sabel, and Robert E. Scott have argued that parties are at least partially self-governing themselves by intertwining governance mechanisms that are enforceable in contract law with those that are not enforceable, most often for want of definiteness.[234] This process is termed "braiding," and the contract that contains these braided mechanisms a "contract for innovation."[235]

---

230 *See supra* note 197, at 697.

231 *See supra* Part I.B.

232 *See supra* note 45.

233 *See Contracting for Innovation*, *supra* note 168, at 451 (explaining that "problems of opportunism and the risk of hold-up. . . seem endemic in . . . interactive collaborative relationships").

234 *Braiding*, *supra* note 169, at 1377.

235 *Id*. Gilson, Sabel, and Scott explain that they "call the legal instrument that facilitates the interfirm collaboration a contract for innovation." *Id*. at 1383.

The Sangamo Biosciences and Shire AG Collaboration and License Agreement discussed above is an example of a braided contract for innovation. In the original agreement, Shire AG was given access to Sangamo's zinc finger DNA-binding technology. The parties came together not for Shire AG to interact just once with Sangamo, but rather for the parties to determine if a further collaboration might produce a viable product using the zinc finger DNA-binding technology. With terms such as "reasonably," "good faith," and "diligent," the parties are able to use these soft terms and thereby allow for subsequent adjustments as needed.[236]

Furthermore, the parties are not bound to purchase or sell in the broad sense of that language from one another, although perhaps it is more accurate to say that the parties are not obligated to develop a product together. The parties *may* develop therapeutic or diagnostic products, yet there is no obligation on the parties beyond making a good faith effort to come up with some product containing the zinc finger technology. With this great level of uncertainty and high level of liability and expense, unexpected events will happen.

A modern MTA, which grants access to needed or desired materials, tools, or data, and additionally opens the door for meaningful shared innovative activity, helps parties respond together to the inevitability of changed circumstances. When more tests are needed, a particular compound is found to be ineffective, clinical trial results are disappointing, etc., they have a decision-making partnership to work through the extra expense and uncertainty.

The biggest downside to a modern MTA is what happens if a breach occurs that the parties cannot resolve internally. A court or arbitration panel will have a difficult time assessing damages in light of the fact that the parties started the relationship, and likely the contract still reflects, that the parties will work together to create "something" in "good faith." That said, parties, like Sangamo and Shire, are putting in place mechanisms that decrease the likelihood of needing a judge to determine liability. Sangamo and Shire, like many other parties, included a formal process that they will go through before seeking the help of any court or arbitration panel. It is called a Joint Steering Committee (JSC). JSCs are common in biotech and pharmaceutical contracts.

Although JSCs are tailored for the specific project and parties, their function and purpose is to construct a decision-making process that will be used when there is disagreement between the contracting parties. JSCs are generally comprised of employees from each contracting party that are designated to serve, and out of that the employees together select a chairperson. The JSC is tasked with finding a reso-

---

[236] *See Contracting for Innovation*, *supra* note 168, at 433-43. The authors explain that using these terms by themselves is insufficient to constrain opportunism because of the moral hazard that one party has "the discretion to adjust performance as conditions change [and] always choos[e] the best alternative for himself." *Id* at 454. While I agree that this is problematic, I think these terms can effectively be used when there is an enforcement mechanism such as a joint steering committee where a more clear definition of required behavior may be decided cooperatively.

lution for any problem that is not easily solved in the laboratory, and if the JSC cannot reach a consensus, then the decision will go to the top executives of the company. It is rare for the JSC to fail to work out the problems. Moreover, it is viewed as a failure and embarrassment if the JSC has to go to the next level of the decision-making process. Overall, the JSC is a great mechanism to help parties solve issues that arise in a modern MTA or other innovative contract where flexible terms are intentionally selected to encourage collaboration and quick changes.

This is particularly true given the problem of enforcing these braided contracts. The particular question that arises is what happens if the JSC fails to reach an agreement on a disputed matter, such as whether to identify a new compound to test when a previous compound fails to meet expectations in testing, and if the CEOs or last level of decision makers also fail to reach a consensus? How does a court or arbitration panel decide something that the parties could not?

Gilson, Sabel, and Scott argue that some courts are already correctly enforcing these contracts by using "low-powered formal enforcement."[237] In contract law terms, low-powered sanctions are not expectation damages. Instead, low-powered sanctions are more akin to reliance or restitution damages. The authors believe the braiding mechanism contained within innovative contracts will work if "[t]he courts are only deploying low-powered incentives; that is, courts sanction only cheating of the parties' mutual commitment to iterative collaboration, but do not attempt to regulate the course or the outcome of the collaboration."[238] In this way, they argue the law should only catch and sanction, as the authors say, "red-faced" violations.[239] Yet these violations of shared innovative activity, where one party simply learns from and then takes from the co-party without working together to create something new, will only have to pay for the non-breaching party's reliance damages, or perhaps disgorge any unjust enrichment that it received from the non-breaching party. This is an undeveloped area of innovative contracting in the shadow of patent law. In many MTAs, parties are contracting in the shadow of patent law, and where patent law has high-powered sanctions in the form of enhanced damages for willful infringement.

We must continue to push forward how parties contracting in the shadow of patent law and using innovative contracting may obtain the protection of higher-powered sanctions, those that will more seriously deter "red-faced" violators. Of course, and as occurs with modern MTAs, sometimes after access is given and an iterative collaborative relationship is established, it turns out not to be a desirable collaboration. Contract law and patent law must be sensitive to the needs of the parties and allow research and collaboration agreements to fail without imposing a

---

[237] *See Braiding*, *supra* note 169, at 1415-16. The authors explain that expectation damages, the general remedy in contract law, are not possible when there is a breached agreement. The expectation was to create something new, and a court will not order the parties to continue working together to create that something that was unidentifiable by the parties themselves. *Id*. at 1425-27.

[238] *Id*. at 1427.

[239] *Id*. at 1417.

sanction that will crowd out or deter future collaborations. I aim to explore in future research how contract law and patent law can best support shared innovation collaboration in the shadow of contract law, one that the modern MTA leads parties to develop.

Conclusion

In this Article, I have identified why MTAs continue to cause delays and frustration despite the fairly simple drafting and language needed: many lawyers and MTA specialists believe that there is just one function and purpose of MTAs when there is actually more than one. A traditional MTA is best used for a quick, one-time transfer of materials when no collaboration or further interaction is desired. A modern MTA is best used when there is a desire for repeated interaction in the form of shared innovative activity. I have argued that parties must recognize the different uses of MTAs. Moreover, I have argued that in order to continue moving forward, science and technology needs collaboration between researchers from across a broad variety of institutions and industries. Using the modern MTA to help develop collaborative relationships has the potential to bring together these diverse researchers, scientists, institutions, and industries.

This Article has also identified that there is still a time and place for a traditional MTA, but even the traditional MTA needs better innovative contracting. The contested terms of indemnification, ownership, and publication rights are slowing the negotiation process and in some cases causing negotiation efforts to fail completely. This hurts innovation and is contrary to the shared goal of bringing new products and technology to the market. I have identified work-around solutions that can make an immediate impact in reducing negotiation time and therefore increasing efficiency in the MTA process.